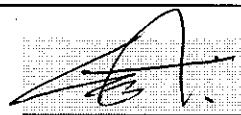
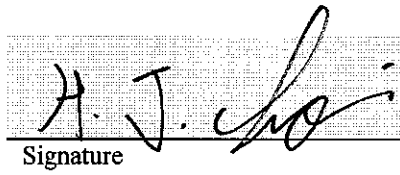
TEST REPORT
MEDICAL ELECTRICAL EQUIPMENT

Equipment / Product	Fetal Monitor
Name and address of the applicant	Bionics Co., Ltd. #2201, Masters Tower, 553, Dohwa-Dong, Mapo-Gu, Seoul, Korea
Name and address of the manufacturer	Bionics Co., Ltd. 214-3, Sangohan-Ri, Hongchun-Eub, Hongchun-Kun, Kangwon-Do, Korea
Name and address of the factory	Bionics Co., Ltd. 214-3, Sangohan-Ri, Hongchun-Eub, Hongchun-Kun, Kangwon-Do, Korea
Trade mark	Bionics
Model/type	IFM-500
Rating and principal characteristics	*0.25-0.15A, 100-240V AC, 50/60Hz* *Cl. I,* Type BF applied part
Serial no	
Tested according to	EN 60601-1 (1990) + A1 (1993) + A2 (1995) +A13 (1996) + Corrigenda (July 1994). MEDICAL ELECTRICAL EQUIPMENT - Part 1: General requirements for safety
Result of testing	***The equipment complies with the above-mentioned standards.***
The test results relate only to the sample(s) tested.	
Name and address of the testing laboratory	Nemko 300-2, Osan-Ri, Mohyun-Myun, Yongin-City Kyungki-Do, Korea Telephone (+82) 31 322 2333 Fax (+82) 31 322 2332
Tested by	 Signature: *Sung-Jin, Woo* Date: *2005-04-07*
Verified by	 Signature: *Hyung-Jun, Choi* Date: *2003-04-07*

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Verdicts are placed in the column to the right.: **P** = Pass, **F** = Fail, **N** = Not applicable, — = Considered/Information.

Due to Nemko's computerised handling of test reports the layout of this form is modified compared to the original TRF published by EMEDCA; 1992-12-01. The content fully covers the original TRF.

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	DESCRIPTION OF EQUIPMENT UNDER TEST:	
	This equipment is a fetal monitor, Fetal heart rate(FHR), fetal movement(FM), and uterine activity(UC) extracted automatically by using Doppler Shift Frequency are displayed and recorded for monitoring up to fetal status. *For description of operating, please refer to User's Manual supplied by Manufacturer.*	
	NAME AND ADDRESS OF PRODUCTION-SITES (FACTORIES):	
	See front page.	
	INFORMATION ABOUT THE STANDARDS / DOCUMENTS CONSIDERED:	
	EN 60601-1 (1990) + A1 (1993) + A2 (1995) +A13 (1996) + Corrigenda (July 1994).	
	EMC standard : EN 60601-1-2 (2001)	
	TESTED ACCORDING TO NATIONAL REQUIREMENTS FOR THE FOLLOWING COUNTRIES:	
	LIST OF APPENDIXES / ENCLOSURES TO THE TEST REPORT:	
	This Part 1 TRF contains **69** *pages, numbered from* **1** *to* **69** *This TRF contains attachments. Attachment #1: Photos. Page* ***1*** *to* ***5***	

SUMMARY OF TESTING

Evaluation of Results

If not explicitly stated otherwise in the standard, the test is passed if the measurement value is equal to or below (above) the limit line, regardless of the uncertainty of the measurement. If the measurement value is above (below) the limit line, the test is not passed - ref. IECEE-CTL Guide 001 and Nemko WM L220.
The instrumentation accuracy is within limits agreed (ref. IECEE-CTL/251A and Nemko procedure WM L226) :

The AC/DC adapter is certified by TÜV Rheinland according to EN60601-1.
(refer to "56. list of Critical Component Parts")
It has double insulation between primary and secondary.

Maximum normal load : Refer to sub-clause 7 (power input)

This equipment was tested with these probes:

- *DOP I*
- *DOP II*
- *UC Probe*
- *Event Mark jack*

Clause	Remarks	Information/Comments
	Cord set not checked	*The equipment shall be provided with a cord set complying with the national regulation of the countries intended for sale*

LIST OF ATTACHMENTS PROVIDING FURTHER INFORMATION ON THE EQUIPMENT TESTED AND THE TEST METHODS

The following attachments are added to this TRF or kept in file at the Testing Station mentioned at the cover page:

Statements on calibrations and measurement uncertainties (where relevant) of the measurement and test equipment as identified throughout this TRF:

Calibration All instruments used in the tests given in this report are calibrated and traceable to international standards.
Further information about tractability will be given on request.

Measurement uncertainties Measurements uncertainties are calculated for all instruments and instruments set-ups given in this report. Calculations are based on the principles given in the standard EA-4/02 (Dec. 1999), IECEE-CTL/153/NF (2002-04-19), Nemko WM L226 and actual internal Nemko procedures. Further information about measurements uncertainties will be given on request

Document title/identification:	*Kept in file at Nemko; P31000*	ATT. No.: *Not attached*

List of worksheets which describe measurement procedures or test methods where practicable:

Document title/identification:	*Kept in file at Nemko; P31000*	ATT. No.: *Not attached*

List of equipment or units tested and/or accompanying units and accessories (in case not all individual units can be mentioned on the front-page):

Document title/identification:	*See summary of testing in this report.*	ATT. No.: *Not attached*

Technical design documents of components having basic, supplementary of reinforced insulation (e.g. transformer specification mentioning the insulation class of the insulation materials applied - A to H):

Document title/identification:	*Kept in file at Nemko*	ATT. No.: *Not attached*

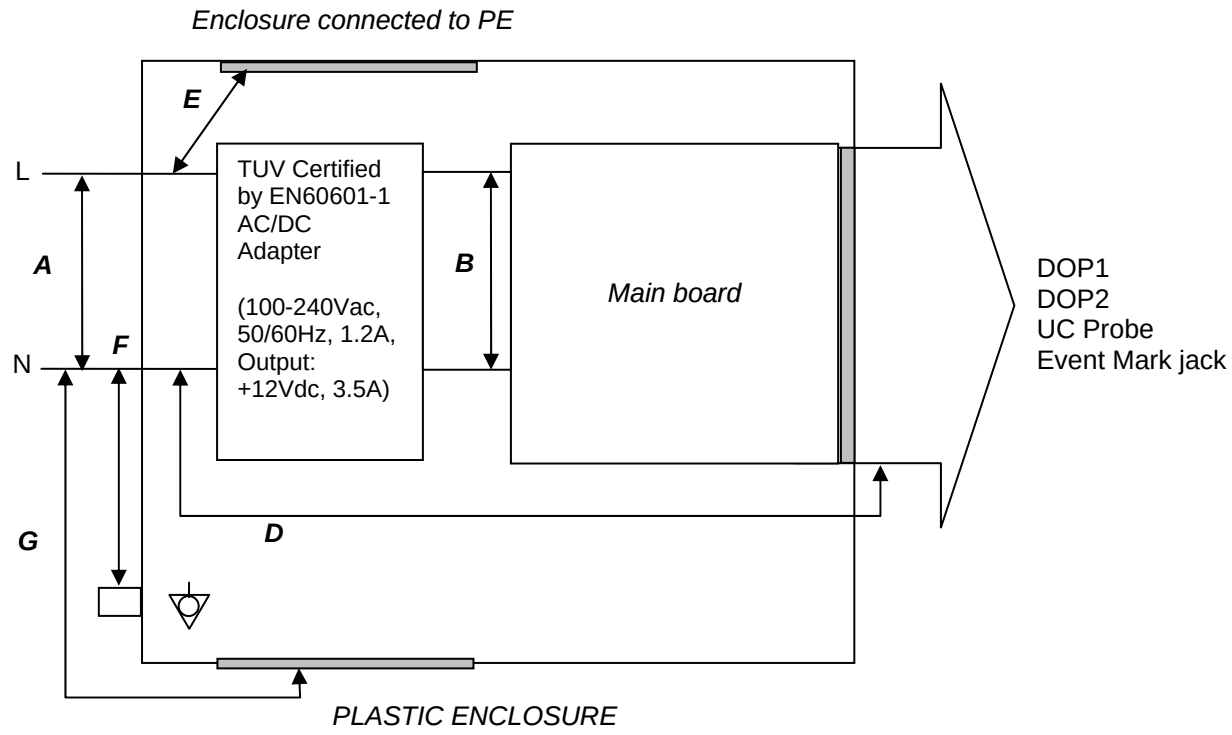
Description of safety systems (specifying for example safety circuits, redundant circuits, double circuits, hardware/software safety measures, temperature controls, etc.):

Document title/identification:	*Kept in file at Nemko*	ATT. No.: *Not attached*

3	GENERAL REQUIREMENTS		
3.1	EQUIPMENT when transported, stored, installed, operated in NORMAL USE and maintained according to the instructions of the manufacturer, causes no SAFETY HAZARD which could reasonably be fore- seen and which is not connected with its intended application in NORMAL CONDITION and in S.F.C.	*The equipment causes no hazards when used according the manufacturers instructions.*	—
3.4	An alternative means of construction is used to that detailed in this standard and it can be demonstrated that an equivalent degree of safety is obtained.	*No alternative construction.*	—

5	CLASSIFICATION		
5.1	Type of protection against electric shock.	*Class I equipment*	
5.2	Degree of protection against electric shock.	*Type BF applied part*	
5.3	Classification of the equipment against ingress of liquids.	*IPX0*	
5.5	Degree of safety of application in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE	*The equipment is not an AP or APG category equipment.*	
5.6	Mode of operation.	*Continuous operation.*	

	INSULATION DIAGRAM		
	Protection against electric shock - Block diagram of system	*Refer to table on next page.*	**P**
Drawing			

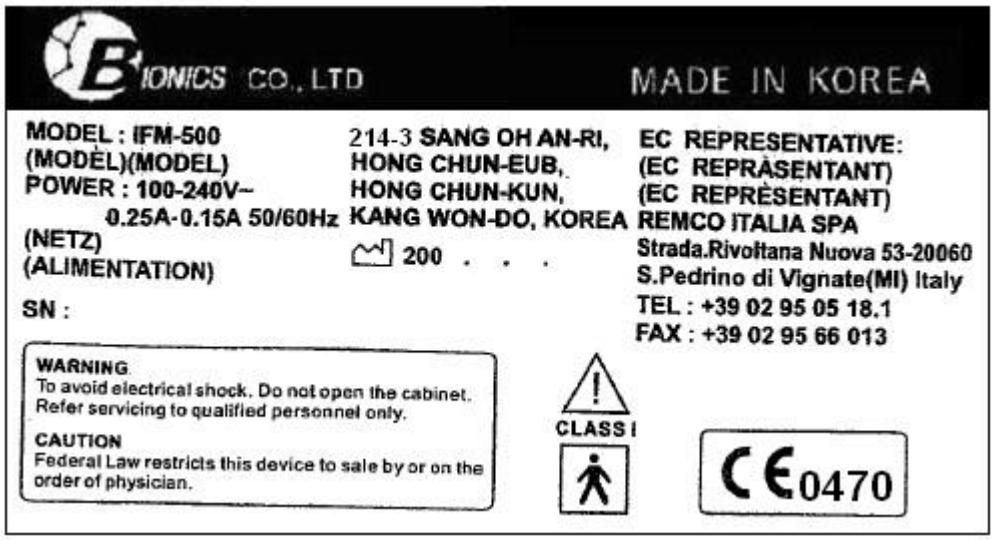


Comments	

TABLE TO INSULATION DIAGRAM ON PREVIOUS PAGE

Area	Distance (Test Refer to 20.1 + 20.2)	Insulation type Basic/Supplement./ Double/Reinforced Insulation	Maximum circuit voltage	Required distances (mm)		Dielectric strength test voltage
				Clearance	Creepage	Refer to 20.3
A	*A-f*	*Basic*	*250 V a.c.*	*1.6 mm*	*3.0 mm*	*Not applicable*
B	*A-f*	*Basic*	*12 V d.c.*	*1.6 mm*	*3.0 mm*	*Not applicable*
D	*B-a*	*Double/Reinforce*	*250 V a.c*	*5.0 mm*	*8.0 mm*	*4 000 V a.c.*
E	*A-a_1*	*Basic*	*250 V a.c.*	*2.5 mm*	*4.0 mm*	*1 500 V a.c.*
F	*A-a_1*	*Basic*	*250 V a.c.*	*2.5 mm*	*4.0 mm*	*1 500 V a.c.*
G	*A-a_2*	*Double/Reinforce.*	*250 V a.c.*	*5.0 mm*	*8.0 mm*	*4 000 V a.c.*
Comments						

6	IDENTIFICATION, MARKING AND DOCUMENTS		
6.1	**Marking on the outside**	*Example of marking label:*	
6.1 a	Markings of Mains operated EQUIPMENT	*See below*	**P**



6.1 b	Markings of Internally Powered EQUIPMENT	*Not applicable. No Internally Powered EQUIPMENT*	**N**
6.1 c	Markings of EQUIPMENT supplied from a specified power supply		**N**
6.1 d	Minimum requirements if limited space for marking	*Symbol 14* *from DI is included in accompanying documents.*	**P**
6.1 e	Name and/or trademark of the manufacturer or supplier	*Bionics*	**P**
6.1 f	Model or type reference	*IFM-500*	**P**
6.1 g	Rated supply voltage(s) or voltage range(s) Number of phases Type of current	*100-240 V* *Single phase* *~*	**P**
6.1 h	Rated frequency or rated frequency range(s) in Hz	*50/60 Hz.*	**P**
6.1 j	Rated power input (VA, W or A)	*0.25-0.15A*	**P**
6.1 k	Power output of auxiliary mains socket outlets	*No socket outlet is provided*	**N**
6.1 l	Class II symbol	*Not applicable.*	**N**
	Symbol for degree of protection with respect to harmful ingress of water according to EN 60529 (IPX0 not required to be marked)	*Ordinary equipment. IPX 0.*	**P**
	Symbol for protection against electric shock:	*Type BF* *. Symbol*	**P**

6.1 m	Mode of operation (if no marking, suitable for continuous operation)	*Continuous operation.*	**N**
6.1 n	Types and rating of external accessible fuses	*"T1AL 250V" marked*	**P**
6.1 p	Rated output voltage and current or power, output frequency (where applicable)	*No auxiliary mains socket outlets.*	**N**
6.1 q	Symbol for physiological effect(s):	*Not applicable. No need for marking.*	**N**
6.1 r	Anaesthetic-proof symbol:	*Not of category AP or APG.*	**N**
6.1 s	High voltage symbol:	*Not applicable. No parts with a voltage over 1 000 V a.c. or over 1 500 V d.c. or 1 500 V peak value.*	**N**
6.1 t	Special cooling requirements	*No special cooling requirements*	**N**
6.1 u)	Limited mechanical stability	*No limited mechanical stability*	**N**
6.1 v	Protective packing requirement(s). Marking(s) for unpacking safety hazard(s)	*No special measures during transport or storage*	**N**
6.1 y	Earth terminals:	*Symbol 9 of table DI, POTENTIAL EQUALIZATION TERMINAL* *is used.*	**P**
6.1 z	Removable protective means	*No removable protective means*	**N**
	Durability of markings	*Tested with a cloth of rack soaked with, in turn, water, methylated spirit and isopropyl alcohol.* *The sample label withstood the test.*	**P**

6.2	**Marking on the inside**		
6.2 a	Marking clearly legible		**P**
	Nominal supply voltage of permanently installed equipment marked inside or outside of equipment	*Not applicable. No permanently installed equipment*	**N**
6.2 b	Maximum power loading of heating elements or lamp holders for heating lamps clearly and indelibly marked near or in the heater	*No heating elements or holders for heating lamps*	**N**
	Heating elements or lamp holders for heating lamps not intended to be changed by operator and which can be changed only with the use of a tool, have at least an identifying marking referring to information stated in the accompanying documents	*Not applicable.*	**N**
6.2 c	High voltage parts:	*No high voltage part*	**N**
6.2 d	Type of battery and mode of insertion (if applicable) marked (see Sub-clause 56.7 b)	*Not applicable.*	**N**
	Batteries not intended be changed by operator and which can be changed only with use of tool have at least marking referring to information in accompanying documents		**N**
6.2 e	Fuse type and rating or reference stated	*Not applicable.*	**N**

6.2 f	Protective earth terminal marked	*Appliance inlet is used in an according to IEC 60320*	**N**
6.2 g	Functional earth terminal marked	*No Functional earth terminal.*	**N**
6.2 h	Terminals for supply neutral conductor in permanently installed equipment marked (N)	*No permanently installed equipment.*	**N**
6.2 j	Markings required in Sub-clause 6.2 f, h, k and l		**P**
6.2 k	The supply connections are clearly marked adjacent to the terminals or in accompanying documents (for small equipment)		**N**
6.2 l	Statement for suitable wiring materials (at temperatures over 75°C) locates at or near the point of the supply connections and is clearly discernible after connection	*Not applicable. No temp. over 75°C.*	**P**
6.2 n	Capacitors and/or circuit parts are marked as required in Sub-clause 15 c	*No such a capacitor*	**N**

6.3	**Marking of controls and instruments**		
6.3 a	Mains switch clearly identified. ”On” and “off” positions marked or otherwise indicated	*“I/O” marked close to the switch on front side*	**P**
6.3 b	Adequate indications of different positions of controls and other switches		**P**
6.3 c	Adequate indication of the direction of setting devices if change of setting of a control could cause a safety hazard		**P**
6.3 f	Functions of operator controls and indicators identified	*All control buttons marked. All functions and marking described in user manual.*	**P**
6.3 g	Numeric indications of parameters are in SI units according to ISO 1000. Units outside the International System as specified	*All control buttons marked. All functions and marking described in user manual.*	**P**

6.4	**Symbols**		
6.4 a	Marking symbols compliance with appendix D, where applicable	*Complied with appendix D, where applicable*	**P**
6.4 b	Symbols for controls and performance conform to IEC 60 878, where applicable		**P**
	Durability of marking symbols	*Tested in Clause 6.1.*	**P**

6.5	**Colours of insulation of conductors**		
6.5 a	Protective earth conductor has green/yellow insulation		**P**
6.5 b	All insulations of internal protective earth conductors are green/yellow, at least at the terminations of the conductors		**P**
6.5 c	Only protective earth-, functional earth-, potential equalisation and inside earthing conductors (cf. 6.5 b) are green/yellow	*Protective earth conductor*	**P**
6.5 d	Colour of neutral conductor: light blue according to IEC 60 227 or 245	*Light Blue*	**P**
6.5 e	Colours of phase conductors in power supply cord according to IEC 60 227 or 245	*Brown, VDE Certified*	**P**
6.5 f	Additional protective earthing in multi-conductor cords are marked green/yellow at the ends of the additional conductors	*No Additional protective earthing*	**N**

6.6	**Identification of medical gas cylinders and connections**		
6.6 a	Identification of content in accordance with ISO/R32	*Not applicable. Not use of medical gas cylinders*	**N**
6.6 b	Identification of connection point that errors are avoided when a replacement is made	*Not applicable.*	**N**

6.7	**Indicator lights and push-buttons**		
6.7 a	Colour red only used for warning of danger or/and need for urgent action. Dot-matrix/alphanumeric displays not considered to be indicator lights	*Not used of colour red.* *The unit used dot-matrix / alphanumeric display*	**P**
6.7 b	Colours of unilluminated push-buttons. Colour red only used in case of emergency	*No emergency switch*	**N**

Location	Meaning of indicator lights	Illuminated push-button (see IEC 60 73)	Colour
Front of enclosure (For "Volume")	*Operating / LED*	*—*	*Green*
Front of enclosure (For "Record")	*Operating / LED*	*—*	*Green*
Front of enclosure (For "Alarm")	*Operating / LED*		*Green*

6.8	**Accompanying documents**		
6.8.1	Equipment is accompanied at least by		
	- instructions for use	*User Manual*	**P**
	- technical description		**P**
	- an address to which the user can refer	*In both the above mentioned booklets*	**P**
	All applicable classifications specified in Clause 5 are included in instructions for use and technical description	*In both the above mentioned booklets*	**P**
	markings in Sub-clause 6.1 included in accompanying documents if not permanently affixed to equipment		**P**
	Warning statements and explanations of warning symbols are provided in accompanying documents	*Properly described in user manual*	**P**
	Language of accompanying documents	*English. Will be in the language required for the market where the equipment is intended to be sold.*	**P**

6.8.2	Instructions for use		
6.8.2 a	General information		
	Necessary information to operate the equipment	*Included in user manual*	**P**
	Explanation of the function of controls, displays and signals	*Included in user manual*	**P**
	Sequence of operation	*Included in user manual*	**P**
	Connection and disconnection of detachable parts and accessories	*Included in user manual*	**P**
	Replacement of material which is consumed during operation	*Included in user manual*	**P**
	Indications of recognised accessories, detachable parts and materials, if the use of other parts or materials can degrade minimum safety	*Included in user manual*	**P**
	Cleaning, preventive inspection and maintenance to be performed including the frequency of such maintenance	*Included in user manual*	**P**
	Information about safe performance of routine maintenance	*Included in user manual*	**P**
	Information about preventive inspection and maintenance to be performed by other persons	*Included in user manual*	**P**
	Meanings of figures, symbols, warning statements and abbreviations on equipment explained in the instructions for use	*Included in user manual*	**P**
	Instruction for use states the function and intended application of equipment	*Included in user manual*	**P**
	Instructions for use provide user with information regarding potential electromagnetic or interference and advice how to avoid such interference	*Included in user manual*	**N**
6.8.2 c	Signal output and signal input parts		
	Signal output or signal input parts intended only for connection to specified equipment stated in instruction for use	*No SIP/SOP parts*	**N**
6.8.2 d	Cleaning, disinfection and sterilisation of parts in contact with the patient		
	Details about cleaning or disinfection or sterilisation methods that may be used for equipment parts which come into contact with the patient during normal use given in instruction for use	*Properly described.*	**P**

6.8.2 e	Mains operated equipment with additional power source		
	A warning statement referring to the necessity for periodical checking or replacement of an additional power source	*This equipment is Alternatively using an internal electrical power source and main supply*	**P**
	If Class I equipment a statement saying that where the integrity of the external protective conductor in the installation or its arrangement is in doubt, equipment shall be operated from its internal electrical power source	*Included in user manual*	**P**
6.8.2 f	Removal of primary batteries (i.e. not rechargeable batteries):		
	Instruction for use contains a warning to remove batteries if equipment is not likely to be used for some time ,unless no risk of safety hazard	*No primary battery*	**N**
6.8.2 g	Rechargeable batteries:		
	Instructions to ensure safe use and adequate maintenance	*Not rechargeable batteries*	**N**
6.8.2 h	Equipment with a specified power supply or battery charger:		
	Instructions for use identify power supplies or battery chargers necessary to ensure compliance with the requirements of IEC 601-1	*Not applicable.*	**N**
6.8.2 j	Instructions for use identify risks associated with disposal of waste, residues etc. and of equipment/accessories at end of their lives. Further it provides advice on minimising these risks	*The item is properly described. Reference to the user Manual.*	**P**
6.8.3	Technical description		
6.8.3 a	General		
	Technical description provides all data essential for safe operation including data in Sub-clause 6.1 and all characteristics of the equipment	*The Technical and Service Manual is well written and contains all necessary information required.*	**P**
	A statement whether particular measures or particular conditions are to be observed for installing equipment and bringing equipment into use		**P**
6.8.3 b	Replacement of fuses and other parts :		
	Required type and rating of fuses utilised in the mains supply circuit external to permanently installed equipment	*No permanently installed equipment*	**N**
	Instructions for replacement of interchangeable and/or detachable parts which are subject to deterioration during normal use	*Properly described.*	**P**

6.8.3 c	Circuit diagrams, component part lists, etc.:		
	The technical description contains a statement that the supplier will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, etc. in order to assist user in case of necessary reparations	*Included in user manual*	**P**
6.8.3 d	Environmental conditions for transport and storage:	*Included in user manual*	
	The technical description contains a specification of the permissible environmental conditions for transport and storage		**P**
	The above said specification also repeated on the outside of the packaging		**P**

7	POWER INPUT(Continued)					
7.1	Steady state current or power input does not exceed the marked rating by more than specified	*Maximum normal load is followings:* *Continuous operation* *1. Applied parts* *(DOPI, DOPII, UC and Event Mark jack)* *2. Max. Volume* *3. Printer*				**P**
	Equipment:	*No. 64*				
	50 Hz supply	*Power input: 100-240VAC, 0.25-0.15A*				**P**
Power input	Function	U_{Nlower} = 90V	***U_N = 100V***	***U_N = 240V***	$U_{N_{upper}}$ = 264V	
Input current	Normal operation (A)	*0.24*	*0.23*	*0.14*	*0.13*	
	Standby (A)	—	—	—	—	
Input power	Normal operation (W)	*12.0*	*12.0*	*13.0*	*13.0*	
Input power	Standby operation (W)	*23.0*	*23.0*	*33.0*	*34.0*	
Power factor	cos φ	*0.52*	*0.52*	*0.39*	*0.38*	
	60 Hz supply	*Power input: 100-240VAC, 0.25-015A*				**P**
Power input	Function	U_{Nlower} = 90V	***U_N = 100V***	***U_N = 240V***	$U_{N_{upper}}$=264V	
Input current	Normal operation (A)	*0.22*	*0.21*	*0.13*	*0.13*	
	Standby (A)	—	—	—	—	
Input power	Normal operation (W)	*12.0*	*12.0*	*13.0*	*13.0*	
Input power	Standby operation (W)	*20.2*	*21.0*	*32.0*	*32.0*	
Power factor	cos φ	*0.57*	*0.55*	*0.40*	*0.39*	

10	ENVIRONMENTAL CONDITIONS		
10.1	Equipment capable, while packed for transport and storage, of being exposed to environmental conditions as stated by manufacturer (see 6.8.3 d)	*Considered OK.*	**P**
10.2	Operation of equipment according to specified environment and power supply	*Considered OK.*	**P**

13	GENERAL		
	Equipment so designed that risk of electric shock obviated as far as practicable (requirements as given in section three)	*Considered OK.*	**P**

14	REQUIREMENTS RELATED TO CLASSIFICATION		
14.1	**Class I equipment**		
14.1 a	Parts with Double Insulation		**N**
	Parts with Reinforced Insulation	*CB Certified adapter used*	**N**
	Parts with SELV-Voltage	*CB Certified adapter used*	**N**
	Parts with Protective Impedance		**N**
14.1 b	If the mains part of equipment specified for an external d.c. power source is isolated from accessible conductive parts by basic insulation only, a separate protective earth conductor is provided	*Not applicable.*	**N**
14.2	**Class II equipment**		
14.2 a	Class II equipment is of one of the following types:	*Not applicable*	**N**
14.2 b	If equipment is fitted with a device for changing over from class I to class II protection, the following requirements are fulfilled:	*Not applicable.*	**N**
	The change-over device indicates the selected class clearly	*Not applicable.*	**N**
	A tool for change-over is necessary	*Not applicable.*	**N**
	The equipment complies with all requirements for the selected class at any given time	*Not applicable.*	**N**
	Class II position: The device interrupts the connection of protective earth conductor to equipment or changes it into functional earth conductor (compliance with 18.2)	*Not applicable.*	**N**
14.2 c	Class II equipment provided with functional earth connections (cf. Sub-clause 18 k and l)	*Not applicable.*	**N**

14.4	**Class I and II equipment**		
14.4 a	Equipment is provided with an additional protection according to the requirements of Class I or Class II equipment		**P**
14.4 b	No safety hazard develop, when a connection with the wrong polarity is made in equipment specified for power supply from an external d.c. power source (e.g. for use in ambulances)		**P**
14.5	**Internally powered equipment**		
14.5 b	Equipment also having means of connection to supply mains complies also with requirements for Class I or II while so connected	*Not applicable. No external d.c. power source*	**N**
14.6	**Types B, BF and CF applied parts**		
14.6 c	Applied parts suitable for direct cardiac application are of type CF	*Type BF*	**N**

15	**LIMITATION OF VOLTAGE AND/OR ENERGY**		
15 b	Equipment with mains plug so designed that the voltage 1 sec. after disconnection does not exceed 60 V	*Certified AC/DC Adaptor*	**N**
	Interference suppression capacitors		**N**
	Capacitance between each line and protective earth. Measured value		**N**
15 c	Accessible live parts of capacitors or related circuits having a residual voltage above 60 V does not have a residual energy above 2 mJ (see 15 c below)	*Not applicable.*	**N**
	A non-automatic discharging device is included and marked	*Not applicable*	**N**

16	ENCLOSURES AND PROTECTIVE COVERS		
16 a	Protection against contact with live parts.	*A tool is needed to open enclosure. No accessible live parts.*	**P**
	- and with parts which can become live in single fault conditions	*A tool is needed to open enclosure. No accessible live parts in single fault condition.*	**P**
	Instruction for use instructs operator not to touch such parts and the patient simultaneously	*Not applicable.*	**N**
	Equipment:	*Standard test finger : No. 97* *Straight test finger : No. 105* *Pull force measuring device : No. 52* *Test pin : No. 98* *Test hook : No. 95* Weight : *approximately 4.2kg*	
Location of opening		Test result (finger, pin, hook)	
Top-side openings		*Pass*	
Rear-side openings		*Pass*	
Bottom-side openings		*Pass*	
16 b	Check of openings in top covers with the vertical suspended test rod	*No holes in enclosure of the unit.*	**P**
16 c	Conductive parts of actuating mechanism of electrical controls after the removal of handles, knobs, levers etc. have either resistance to the protective earth terminal max. 0.2 ohms or the separation from live parts complies with 17 g	*No handles, knobs, levers for removal*	**N**
16 d	Protection of contact with internal parts of the equipment with a circuit voltage exceeding 25 V a.c. or 60 V d.c. which cannot be disconnected from the supply by external mains switch or plug device	*No parts exceeding 25V ac, or 60Vdc*	**N**
16 e	Protective enclosures are removable only with the aid of tool or an automatic device makes these parts not live, when the enclosure is opened or removed	*Screw driver is required to remove enclosures*	**P**
16 f	Live parts are inaccessible to the test rod through openings for adjustment of pre-set controls		**N**

17	SEPARATION		
17 a	Separation method of the applied part from live parts so that allowable leakage currents are not exceeded		
17 a 1	Basic insulation - applied part earthed	*Not applicable.*	**N**
17 a 2	By protectively earthed conductive part (e.g. screen)	*Not applicable.*	**N**
17 a 3	By separate earthed intermediate circuit	*Not applicable.*	**N**
17 a 4	By double or reinforced insulation	*DOP I, DOP II, UC Probe and Event Mark jack*	**P**
17 a 5	By protective impedances limiting current to applied part	*See table 19*	**P**
17 a 6	Other method, e.g. specified in particular standard	*Not applicable.*	**N**
17 c	There is no conductive connection between applied parts and accessible conductive parts, which are not protectively earthed	*All accessible conductive parts are protectively earthed.*	**P**
17 d	Supplementary insulation between hand-held flexible shafts and motor shafts (Class I equipment)	*No such a part*	**N**
	Adequate isolation of accessible metal parts from motor shaft		**N**
	Rated motor voltage		**N**
	Test voltage		**N**
	Air clearances/creepage distances (mm)/(mm)		**N**
17 g	Separation method of accessible parts other than applied parts from live parts so that allowable leakage currents are not exceeded	*Protectively earthed and the applied part has such a low internal impedance to earth that leakage currents do not exceed the allowable values in normal condition and single fault condition.*	**P**
17 g 1	Basic insulation - accessible part earthed	*See above 1) and below 4)*	**N**
17 g 2	By protectively earthed conductive part (e.g. screen)	*See above 1) and below 4)*	**N**
17 g 3	By separate earthed intermediate circuit	*Unearthed part to mains parts(see insulation diagram)*	**P**
17 g 4	By double or reinforced insulation	*See above 1) and 4)*	**P**
17 g 5	By protective impedances limiting current to accessible part	*See above 1) and 4)*	**P**
	Leakage currents measurements, when required	*Protectively earthed and the applied part has such a low internal impedance to earth that leakage currents do not exceed the allowable values in normal condition and single fault condition.*	**P**

17 h	Adequate arrangements used to isolate defibrillation-proof applied parts from other parts	*No defibrillation-proof applied parts*	**N**
	Impulse voltage tests		**N**
	Peak voltage between Y1 and Y2 does not exceed 1 V		**N**
	After recovery time equipment continues to perform its intended function		**N**

18	PROTECTIVE EARTHING, FUNCTIONAL EARTHING AND POTENTIAL EQUALIZATION		
18 a	Sufficiently low impedance to the protective earth terminal(18 f and 18 g)	*See 18 f)*	**P**
18 b	Suitable connection between protective earth terminal and protective conductor in the installation (18 f)		**P**
18 e	Means for connection of potentially equalisation conductor complies with specified requirements		**P**
	This connection complies with following requirements:		**P**
	- readily accessible		**P**
	- no possibility to accidental disconnection in normal use		**P**
	- conductor is detachable without the use of a tool		**P**
	- power supply cord does not include potential equalisation conductor		**P**
	- connection is marked with symbol		**P**
18 f	Impedance of protective earthing system: Impedance between any accessible metal part and: 1) protective earth terminal (PE) (requirement: R max. 0.1 Ohm), 2) protective earth contact in appliance inlet (requirement: R max. 0.1 Ohm), 3) protective earth contact in the mains plug Test equipment: See attached list. (requirement: R max. 0,2 Ohm), are tabled below:		**P**

Accessible part and its location	R (Ohm) measured against (numbers see above)		
	1 PE	2 inlet	3 plug
Gnd of Inlet - Accessible metal part	—	*0.02*	—
Gnd of Inlet –Probe connector	—	*0.021*	—
Gnd of Inlet – Potential equalization connector	—	*0.018*	—

18 g	If the impedance of protective earth connections other than in 18 f exceeds 0.1 Ohm, the allowable value of the enclosure leakage current is not exceeded in single fault condition	*Not applicable*	**N**
18 k	Functional earth terminals are not used to provide protective earthing	*No functional earth*	**N**

18 l	For Class II equipment with isolated internal screens and with a power supply cord:	*Not applicable. Class I equipment.*	**N**
	- the third conductor is used only as functional earth of these screens and is coloured green/yellow		**N**
	- insulation of such screens and all internal wiring connected to them is double insulation or reinforced insulation (see also 20.3)		**N**
	- marking of functional earth terminal is distinguished from protective earth terminal and is explained in accompanying documents		**N**
	Test of insulation (see Clause 20)		**N**

19	CONTINUOUS LEAKAGE CURRENTS AND PATIENTS AUXILIARY CURRENTS		
19.1	General requirements (tests see 19.4)		
19.1 g	Equipment with multiple patient connections: Patient leakage current and patient auxiliary current do not exceed allowable values while one or more patient connections are disconnected from the patient or disconnected from the patient and earthed		P
19.2	Single fault conditions (tests see 19.4)		
19.3	Allowable values (see 19.4)		
19.4	Tests before humidity preconditioning treatment	*See comment below.*	
	Equipment:	*Mains voltage : No. 83* *AC-voltage : No. 19* *DC-voltage : No.19* *MD : 03* *Equipment for supply connection normal or reverse: 06*	

Type of leakage current	In normal condition		In single fault condition		
	Allowed value (µA)	Measured max. value (µA)	Allowed value (µA)	Measured max. value (µA)	
Earth leakage current	500	*246*	1000	*453*	
Enclosure leakage current	100	*56.3*	500	*57.3*	
Patient leakage current (p.l.c.), a.c. :	B, BF: 100 CF: 10	*58.7*	B, BF: 500 CF: 50	*59.3*	
Patient leakage current (p.l.c.), d.c. :	B, BF: 10 CF: 10	*0.01*	B, BF: 50 CF: 50	*0.01*	
P.l.c. (110 % of the mains voltage on the signal input part or signal output part)	—	*—*	B: 5000 BF, CF: —	*—*	
P.l.c. (110 % of mains voltage on the applied part)	—	*—*	B: — BF: 5000 CF: 50	*45.9*	
Patient auxiliary current, a.c. :	B, BF: 100 CF: 10	*42.1*	B, BF: 500 CF: 50	*47.5*	
Patient auxiliary current, d.c. :	B, BF: 10 CF: 10	*0.01*	B, BF: 50 CF: 50	*0.01*	

Comments	
	The values listed are the maximum values.

19.4	Tests after humidity preconditioning treatment	*See comments below.*	
	Equipment:	*Mains voltage : No. 83* *AC-voltage : No. 19* *DC-voltage : No.19* *MD : 03* *Equipment for supply connection normal or reverse: 06*	

Type of leakage current	In normal condition		In single fault condition		
	Allowed value (µA)	Measured max. value (µA)	Allowed value (µA)	Measured max. value (µA)	
Earth leakage current	500	*249*	1000	*459*	
Enclosure leakage current	100	*56.7*	500	*56.8*	
Patient leakage current (p.l.c.), a.c. :	B, BF: 100 CF: 10	*58.9*	B, BF: 500 CF: 50	*59.5*	
Patient leakage current (p.l.c.), d.c. :	B, BF: 10 CF: 10	*0.01*	B, BF: 50 CF: 50	*0.01*	
P.l.c. (110 % of the mains voltage on the signal input part or signal output part)	—	*—*	B: 5000 BF, CF: —	*—*	
P.l.c. (110 % of mains voltage on the applied part)	—	*—*	B: — BF: 5000 CF: 50	*46.2*	
Patient auxiliary current, a.c. :	B, BF: 100 CF: 10	*42.4*	B, BF: 500 CF: 50	*47.8*	
Patient auxiliary current, d.c. :	B, BF: 10 CF: 10	*0.01*	B, BF: 50 CF: 50	*0.01*	

Comments		
	The values listed are the maximum values.	

20	DIELECTRIC STRENGTH (at operating temperature)				
	Overall compliance with Clause 20				
	Equipment:		*High voltage supply : No. 61*		
Equipment	Insulation under test	Insulation resistance *)	Reference voltage	Test voltage	Remarks, observations
All Equipment Types	A-a_1		*250 V AC*	*1 500 V AC*	*No Breakdown*
	A-a_2		*250 V AC*	*4 000 V AC*	*No Breakdown*
	A-e		*250 V AC*	*4 000 V AC*	*No Breakdown*
Equipment Types with Applied part	B-a		*250 V AC*	*4 000 V AC*	*No Breakdown*
	B-a **		*5 V DC*	*500 V AC*	*No Breakdown, (DOPI, DOPII, UC and Event Mark jack)*

*) IEC 601-1 does not require to measure this
**) Conducted the test between probe face and patient port

20	DIELECTRIC STRENGTH (after humidity preconditioning treatment)				
	Overall compliance with Clause 20				
	Equipment:		*Humidity room : No. 72* *High voltage supply : No. 61*		
Equipment	Insulation under test	Insulation resistance *)	Reference voltage	Test voltage	Remarks, observations
All Equipment Types	A-a_1		*250 V AC*	*1 500 V AC*	*No Breakdown*
	A-a_2		*250 V AC*	*4 000 V AC*	*No Breakdown*
	A-e		*250 V AC*	*4 000 V AC*	*No Breakdown*
Equipment Types with Applied part	B-a		*250 V AC*	*4 000 V AC*	*No Breakdown*
	B-a **		*5 V DC*	*500 V AC*	*No Breakdown, (DOPI, DOPII, UC and Event Mark jack)*

*) IEC 601-1 does not require to measure this
**) Conducted the test between probe face and patient port

21	MECHANICAL STRENGTH		
21 a	Rigidity of enclosure (45 N test force)	*Tested with 45 N. No damage to enclosure parts.*	**P**
21 b	Strength of enclosure part and any component thereon (Impact hammer test, 0.5 J).	*No damage resulting in a safety hazard.*	**P**
21 c	On portable equipment carrying handles or grips withstand the requirements of the loading test. (Test force four times the weight of equipment)	*Handle(16.8kg; 1min)*	**P**
21.3	No damage to parts of patient support and/or immobilisation system after the loading test (1350 N and 2700 N tests)	*Not applicable.*	**N**
	The test force for foot rests and chairs shall be twice the specified maximum load or, if not specified, the test force shall be 2,7 kN. The test force shall be distributed over an area of 0,1 m^2 surface for 1 minute.	*Not applicable.*	**N**
21.5	Hand-held equipment or equipment parts are safe after drop test (dropping height 1 m)	*Probes (1m : 3times)*	**P**
21.6 a	Portable and mobile equipment is able to withstand rough handling.	*No damage resulting in a safety hazard. (Drop height is 5cm)*	**P**
21.6 b	Propel test of mobile equipment (performed 20 times). Equipment complies with requirements of this standard.	*Not applicable.*	**N**

22	MOVING PARTS		
22.2 a	Moving parts of transportable equipment are provided with guards which form an integral part of the equipment	*Not applicable.*	**N**
22.2 b	Moving parts of stationary equipment are provided with similar guards as above unless it is evident that equivalent protection is separately provided during installation	*Not applicable.*	**N**
22.3	Cords (ropes), chains and bands are confined so they cannot run off or jump out of their guiding devices	*Not applicable.*	**N**
	Other means used to prevent a safety hazard	*Not applicable.*	**N**
	Mechanical safeguard means are removable only with a tool	*Not applicable.*	**N**
22.4	Dangerous movements of equipment parts, which may cause physical injury to the patient, are possible only by the continuous activation of the control	*Not applicable.*	**N**
22.6	Parts of equipment subject to mechanical wear are accessible for inspection	*Not applicable.*	**N**
22.7	To remove an unexpected safety hazard caused by an electrically produced mechanical movement, there are means for emergency switching of a relevant part	*Not applicable.*	**N**
	The means for emergency switching are readily identifiable and accessible and do not introduce a further safety hazard	*Not applicable.*	**N**
	Current breaking capability	*Not applicable.*	**N**
	Means for stopping of movements operate as a result of one single action	*Not applicable.*	**N**

23	SURFACES, CORNERS AND EDGES		
	There are no rough surfaces, sharp corners, flange or frame edges and burrs which may cause injury or damage	*The edges are well rounded.*	**P**

24	STABILITY IN NORMAL USE		
24.1	Equipment does not overbalance, when tilted through an angle of 10°	*Tested.*	**P**
24.3	If equipment overbalances when tilted 10°, it does not overbalance when tilted:	*Not applicable. See above*	**N**
	- 5° in any position of normal use, excluding transport		**N**
	- 10° in the condition specified for transport		**N**
	The equipment carries a warning notice for transport		**N**
24.6 a	Equipment or its parts with a mass of more than 20 kg:	*Not applicable.*	**N**
	- is provided with handling devices (grips etc.)		**N**
	- is provided with handling instructions for lifting and assembling		**N**
24.6 b	Portable equipment with a mass of more than 20 kg carrying handle(s) suitably placed that equipment may be carried by 2 or more persons	*Mass of 4.2kg*	**N**

25	EXPELLED PARTS		
25.1	Protective means are provided where expelled parts of the equipment could constitute a safety hazard	*Not applicable. No expelled parts.*	**N**
25.2	Display vacuum tubes with a face dimension of 16 cm or larger are intrinsically safe with respect to effects of implosion of tubes and to mechanical impact, or the enclosure of the equipment is provided with adequate protection against implosion	*Not applicable.*	**N**
	Certificate of the test provided		**N**

26	VIBRATION AND NOISE		
		No general requirement.	

27	PNEUMATIC AND HYDRAULIC POWER		
		No general requirement.	

28	SUSPENDED MASSES		
28.3	Suspension systems with safety devices:	*Not applicable.*	**N**
	Suspension systems include a safety device with adequate safety factors to protect user or patient from hazards	*Not applicable.*	**N**
	If after activation of a safety device the equipment can still be used, the activation of the device, e.g. a secondary rope, becomes obvious to the operator		**N**
28.4	Suspension systems of metal without safety devices:		**N**
	The construction of the suspension complies with:		**N**
28.4 1	The TOTAL LOAD does not exceed the SAFE WORKING LOAD	*No suspension system*	**N**
28.4 2	Where it is unlikely that supporting characteristics will be impaired by wear, corrosion, material fatigue or ageing, the SAFETY FACTOR of all supporting parts is not less than 4	*See above*	**N**
28.4 3	Where impairment by wear, corrosion, material fatigue is expected, the SAFETY FACTOR is not less than 8	*See above*	**N**
28.4 4	Where metal having a specific elongation at break of less than 5% is used in supporting components, the SAFETY FACTOR is not less than 1.5 times those given in 2) and 3) above	*See above*	**N**
28.4 5	Sheaves, sprockets, band wheels and guides are so designed that the SAFETY FACTORS of this Sub-clause shall be maintained for a specified minimum life till replacement of the ropes, chains and bands	*See above*	**N**
28.5	Dynamic loads:	*No general requirement.*	

29	X-RADIATION		
29.1	Diagnostic X-ray equipment, see IEC 601-1-3. Radiotherapy equipment, see relevant Particular standard	*Not applicable.*	**N**
29.2	For equipment not intended to produce X-radiation for diagnostic and therapeutic purposes, ionising radiation emitted by vacuum tubes excited by voltages exceeding 5 kV does not produce an exposure exceeding 130 nC/kg (0.5 mR)	*Not applicable.*	**N**

30	ALPHA, BETA, GAMMA, NEUTRON RADIATION AND OTHER PARTICLE RADIATION		
		No general requirement.	

31	MICROWAVE RADIATION		
		No general requirement.	

32	LIGHT RADIATION (INCLUDING LASERS)		
		No general requirement.	

33	INFRA-RED RADIATION		
		No general requirement.	

34	ULTRAVIOLET RADIATION		
		No general requirement.	

35	ACOUSTICAL ENERGY (INCLUDING ULTRA-SONICS)		
		No general requirement.	

36	ELECTROMAGNETIC COMPATIBILITY		
	EN 60601-1-2 (2001)	*Compliance documented by the manufacturer.*	**P**

37 - 41	REQUIREMENTS FOR CATEGORY AP AND APG EQUIPMENT		
	See additional test report form.		**N**

42	EXCESSIVE TEMPERATURES		
	Ambient temperature during measurements:	*See tables below.*	
	Humidity:	*70%*	
	Atmospheric pressure:	1002hpa	
	Equipment:	Humidity : 72	
42.1 - 42.2	Determination of the temperature with thermocouples:		**P**
	Equipment:	*No. 42*	

Quantity	Rated	Used in tests	Remarks
Supply voltage, V	*100-240V AC, 50/60Hz*	*90 V AC / 60Hz*	***Heating*** *Maximum normal load : Refer to sub-clause 7(power input)*
Supply power, VA	—	—	Calculated temp. T (°C)

Measuring point	Measured temp. Δt (°K)	Measured max. temp. T (°C)	Calculated temp. T (°C)	Allowed max. temp. T (°C)	Remarks
1. Ambient	—	*26.5*	—	—	
2. AC inlet	*0.4*	*26.9*	*40.4*	*85.0*	*Added the 40°C*
3. Wire between AC inlet and Mains switch	*8.9*	*35.4*	*48.9*	*105.0*	*Added the 40°C*
4. Body of Main switch	*1.5*	*28.0*	*41.5*	*85.0*	*Added the 40°C*
5. Body of Motor	*26.0*	*52.5*	*66.0*	*110.0*	*Added the 40°C*
6. PCB near U15(main board)	*8.7*	*35.2*	*33.7*	*105.0*	*Added the 25°C*
7. PCB near U14(main board)	*10.1*	*36.6*	*35.1*	*105.0*	*Added the 25°C*
8. Coil of Transformer (AC/DC Adapter)	*19.0*	*45.5*	*59.0*	*130.0*	*Added the 40°C*
9. Body of enclosure (AC/DC Adapter)	*6.7*	*33.2*	*31.7*	—	*Added the 25°C*
10. Top enclosure	*3.6*	*30.1*	*43.6*	*85.0*	*Added the 40°C*
11. "Record" button	*5.4*	*31.9*	*45.4*	*85.0*	*Added the 40°C*
12. Applied part(DOP I)	*0.5*	*27.0*	*40.5*	*41.0*	*Added the 40°C*
13. Applied part(DOP II)	*0.8*	*27.3*	*40.8*	*41.0*	*Added the 40°C*
14. Applied part(UC)	*0.7*	*27.2*	*40.7*	*41.0*	*Added the 40°C*
15. Applied part(event Mark jack)	*0.8*	*27.3*	*40.8*	*41.0*	*Added the 40°C*

Comments	According to IEC 601-1 clause 42.1, table Xa and Xb, 40^0C or 25^0C is added to the temperature rise for determination of the final temperature T.

42	EXCESSIVE TEMPERATURES		
42.1 - 42.2	Determination of the temperature with thermocouples:		P
	Equipment:	*No. 42*	

Quantity	Rated	Used in tests	Remarks
Supply voltage, V	*100-240V AC, 50/60Hz*	*264 V AC / 50Hz*	***Heating*** *Maximum normal load : Refer to sub-clause 7(power input)*
Supply power, VA	—	—	Calculated temp. T (°C)
Output power, VA	—	—	

Measuring point	Measured temp. Δt (°K)	Measured max. temp. T (°C)	Calculated temp. T (°C)	Allowed max. temp. T (°C)	Remarks
1. Ambient	—	*25.8*	—	—	
2. AC inlet	*0.1*	*25.9*	*40.1*	*85.0*	*Added the 40°C*
3. Wire between AC inlet and Mains switch	*9.2*	*35.0*	*49.2*	*105.0*	*Added the 40°C*
4. Body of Main switch	*0.1*	*25.9*	*40.1*	*85.0*	*Added the 40°C*
5. Body of Motor	*28.4*	*54.2*	*68.4*	*110.0*	*Added the 40°C*
6. PCB near U15(main board)	*7.9*	*33.7*	*32.9*	*105.0*	*Added the 25°C*
7. PCB near U14(main board)	*9.5*	*35.3*	*34.5*	*105.0*	*Added the 25°C*
8. Coil of Transformer (AC/DC Adapter)	*27.5*	*53.3*	*67.5*	*130.0*	*Added the 40°C*
9. Body of enclosure (AC/DC Adapter)	*7.0*	*32.8*	*32.0*	*-*	*Added the 25°C*
10. Top enclosure	*3.3*	*29.1*	*43.3*	*85.0*	*Added the 40°C*
11. "Record" button	*3.6*	*29.4*	*43.6*	*85.0*	*Added the 40°C*
12. Applied part(DOP I)	*0.5*	*26.3*	*40.5*	*41.0*	*Added the 40°C*
13. Applied part(DOP II)	*0.7*	*26.5*	*40.7*	*41.0*	*Added the 40°C*
14. Applied part(UC)	*0.5*	*26.3*	*40.5*	*41.0*	*Added the 40°C*
15. Applied part(event Mark jack)	*0.2*	*26.0*	*40.2*	*41.0*	*Added the 40°C*

Comments	According to IEC 60601-1 clause 42.1, table Xa and Xb, 40^0C or 25^0C is added to the temperature rise for determination of the final temperature T.

42	EXCESSIVE TEMPERATURES		
42.1 - 42.2	Determination of the temperature with thermocouples:		P
	Equipment:	*No. 42*	

Quantity	Rated	Used in tests	Remarks
Supply voltage, V	*100-240V AC, 50/60Hz*	*264 V AC / 50Hz*	***Blocked opening*** *Maximum normal load : Refer to sub-clause 7(power input)*
Supply power, VA	—	—	Calculated temp. T (°C)
Output power, VA	—	—	

Measuring point	Measured temp. Δt (°K)	Measured max. temp. T (°C)	Calculated temp. T (°C)	Allowed max. temp. T (°C)	Remarks
1. Ambient	—	*26.5*	—	—	
2. AC inlet	*0.4*	*26.9*	*40.4*	*127.0*	*Added the 40°C*
3. Wire between AC inlet and Mains switch	*8.9*	*35.4*	*48.9*	*161.0*	*Added the 40°C*
4. Body of Main switch	*1.5*	*28.0*	*41.5*	*127.0*	*Added the 40°C*
5. Body of Motor	*26.0*	*52.5*	*66.0*	*169.5*	*Added the 40°C*
6. PCB near U15(main board)	*8.7*	*35.2*	*33.7*	*161.0*	*Added the 25°C*
7. PCB near U14(main board)	*10.1*	*36.6*	*35.1*	*161.0*	*Added the 25°C*
8. Coil of Transformer (AC/DC Adapter)	*19.0*	*45.5*	*59.0*	*203.5*	*Added the 40°C*
9. Body of enclosure (AC/DC Adapter)	*6.7*	*33.2*	*31.7*	*-*	*Added the 25°C*
10. Top enclosure	*3.6*	*30.1*	*43.6*	*127.0*	*Added the 40°C*
11. "Record" button	*5.4*	*31.9*	*45.4*	*127.0*	*Added the 40°C*
12. Applied part(DOP I)	*0.5*	*27.0*	*40.5*	*41.0*	*Added the 40°C*
13. Applied part(DOP II)	*0.8*	*27.3*	*40.8*	*41.0*	*Added the 40°C*
14. Applied part(UC)	*0.7*	*27.2*	*40.7*	*41.0*	*Added the 40°C*
15. Applied part(event Mark jack)	*0.8*	*27.3*	*40.8*	*41.0*	*Added the 40°C*

Comments	According to IEC 60601-1 clause 42.1, table Xa and Xb, 40^0C or 25^0C is added to the temperature rise for determination of the final temperature T.

43	**FIRE PREVENTION**		
43.1	Strength and rigidity of the equipment are sufficient to avoid fire hazards (see 21)	*The equipment is well constructed with regard to avoid fire hazard.*	**P**
43.2	Oxygen enriched atmospheres:	*No general requirement.*	

44	**OVERFLOW, SPILLAGE, LEAKAGE, HUMIDITY, INGRESS OF LIQUIDS, CLEANING, STERILIZATION, DISINFECTION AND COMPATIBILITY**		
44.2	**Overflow**		
	Equipment containing a liquid reservoir:	*Not applicable. No use of liquid containers or liquids in normal operation*	**N**
	- The equipment is electrically safe after 15% overfill steadily over a period of 1 min		**N**
	- Transportable equipment is electrically safe after additionally having been tilted through 15° in least favourable direction(s) (if necessary with refilling)		**N**
	No signs of wetting of uninsulated live parts		**N**
	Dielectric strength test (if deemed necessary)		**N**
44.3	**Spillage**		
	Safety of the equipment does not change in consequence of spillage test performed by the method mentioned in the standard (200 ml of water for approximately 15 s from a height of max. 5 cm)		**P**
44.4	**Leakage**		
	Safety of the equipment does not change in consequence of leakage test performed by the method mentioned in the standard (drops of water). Equipment shall be so constructed that liquid which might escape in a single fault condition does not cause a safety hazard(see also Sub-clause *52.4.1)	*Not applicable. No use of liquid containers or liquids in normal operation*	**N**
44.5	**Humidity**		
	Checked by the pre-conditioning treatment and tests (see 4.10)	*32℃, 93%, 48hr*	**P**

44.6	**Ingress of liquids**		
	Equipment checked by relevant tests of IEC 60 529	*Not applicable.*	**N**
	Equipment withstands dielectric strength test in Clause 20.		**N**
	Water, if entered equipment, has no harmful effect, in particular there is no trace of water on insulation for which creepage distances are specified		**N**
44.7	**Cleaning, sterilisation and disinfection**		
	Equipment/equipment parts capable of withstanding cleaning, sterilisation or disinfection likely to be encountered in normal use or specified by the manufacturer	*See Sub-clause 6.8.2 d.*	**P**
	Test with saturated steam at 134 degrees C+-4 for 20 cycles, each of 20 min duration	*Cleaning instructions given in user manual.*	**N**
	Method specified by the manufacturer in instructions for use	*See Sub-clause 6.8.2 d.*	**P**
	Safety of the equipment not impaired by the test. No appreciable signs of deterioration. Dielectric strength test specified in Clause 20. withstood.		**N**
44.8	**Compatibility with substances used with the equipment:**	*No general requirement*	

45	**PRESSURE VESSELS AND PARTS SUBJECT TO PRESSURE**		
45.2	Pressure vessel with a pressure volume greater than 200 kPa x l, and pressure greater than 50 kPa, withstands the hydraulic test pressure.	*Not applicable. No pressure vessel.*	**N**
	Hydraulic test pressure: (The test pressure shall be maximum permissible working pressure multiplied by a factor obtained from Fig. 38).		**N**
45.3	The maximum pressure to which a part can be subjected in normal condition and single fault condition does not exceed the maximum permissible working pressure for the part		**N**
	The used maximum pressure is the highest of the following:		**N**
45.3 a	Rated maximum supply pressure from an external source		**N**
45.3 b	Pressure setting of a pressure relief device provided as part of the assembly		**N**

45.3 c	Maximum pressure that can be developed by an air compressor that is part of the assembly, unless the pressure is limited by a pressure-relief device		**N**
45.7	Equipment incorporates pressure-relief device(s) where excessive pressure could occur		**N**
	If yes, it complies with all the following requirements:		**N**
45.7 a	Connected as close as possible to the pressure vessel or parts of system it is intended to protect		**N**
45.7 b	Readily accessible for inspection, maintenance and repair		**N**
45.7 c	Not capable of being adjusted or rendered inoperative without a tool		**N**
45.7 d	Its discharge opening located and directed so, that released materials is not directed towards any person		**N**
45.7 e	Operation of device does not deposit material on parts causing possible safety hazard		**N**
45.7 f	Ensures that the pressure does not exceed the maximum permissible working pressure by more than 10%, if a failure occurs in the control of the supply pressure		**N**
45.7 g	No shut-off valve between the pressure-relief device and the parts it is intended to protect		**N**
45.7 h	Minimum number of cycles of operation is 100 000, except for bursting disks		**N**

46	HUMAN ERRORS		
		No general requirement.	

47	ELECTROSTATIC DISCHARGES		
		No general requirement.	

48	BIOCOMPATIBILITY		
	Equipment parts and accessories intended to come into contact with biological tissues, cells or body fluids assessed and documented as given in ISO 10993-1. Inspection of information provided by manufacturer.	*According to the information provided by the manufacturer the equipment is considered to comply with the requirements.*	**P**

49	INTERRUPTION OF POWER SUPPLY		
49.1	If automatically resetting thermal cut-outs and overcurrent releases are used, they give a safe condition by such resetting	*Not applicable.*	**N**
49.2	Interruption and restoration of the power supply do not result in hazards	*No hazard in case of interruption of power supply*	**P**
49.3	Means are provided for removal of mechanical constrains on patients in case of a supply mains failure		**N**

50	MARKING OF CONTROLS AND INSTRUMENTS		
50.1		*See Sub-clause 6.3.*	

51	PROTECTION AGAINST HAZARDOUS OUTPUT		
51.1	**Intentional exceeding of safety limits.**	*No general requirement (cf. Appendix A, Sub-clause A2)*	
51.2	**Indication of parameters relevant to safety.**	*No general requirement (cf. Appendix A, Sub-clause A2)*	
51.3	**Reliability of components.**	*See Sub-clause 3.6 f.*	
51.4	Equipment providing both low- and high-intensity outputs. Minimised possibility of high intensity output being selected accidentally	*The intended purpose of this equipment is not treatment*	**N**
51.5	**Incorrect output.**	*No general requirement*	

52	ABNORMAL OPERATION AND FAULT CONDITIONS		
52.1	Equipment shall be so designed and manufactured that even in single fault condition no safety hazard as described under Sub-clause 52.4 exists (see 3.1 and 13)		P
52.1	Safety of equipment incorporating programmable electronic systems (PES) conforms to the rules of future IEC 601-1-4	*Manufacturer risk analysis was reviewed*	P
52.5.1	Overloading of mains supply transformers	*Not applicable*	N
52.5.2	Failure of thermostats	*Not applicable.*	N
52.5.3	Short-circuiting one part of a double insulation	*Not applicable.*	N
52.5.4	Interruption of the protective earth conductor (tests as described in Sub-clause 19.4)	*See Sub-clause 19.4*	P
52.5.5	Impairment of cooling. Temperatures do not exceed 1.7 times values of Clause 42, Tables Xa and Xb, minus 17.5 degrees C.	*Blocked openings, See clause 42*	P
52.5.6	Locking of moving parts (see also 52.5.8)	*See the table of clause 52.5.9.*	P
52.5.7	Interruption and short-circuiting of motor capacitors (see also 52.5.8)	*Not applicable.*	N
52.5.8	Additional tests for motor operated equipment:	*See clause 52.5.6*	P
52.5.9	Failure of components (refer to Table in Clause 56)		P
	X1 and X2 capacitors between parts of opposite polarity in the mains part and complying with IEC 60 384-14 exempted from this requirement	*No capacitor*	
52.5.10	Overload		
52.5.10 a	Equipment with heating elements:	*No heating elements*	N
52.5.10 a 1	Thermostatically controlled equipment (see 52.5.10.c and d)		N
52.5.10 a 2	Equipment with heating elements with short-time rating (see 52.5.10 c and e)		N
52.5.10 a 3	Other equipment with heating elements (see 52.5.10 c)		N
52.5.10 b	Equipment having motors, which are a part of equipment (see 52.5.5 - 52.5.8 and 52.5.10 f - 52.5.10 h)	*Not applicable.*	N

52.5.10 b 1	Mention circuit/component concerned (e.g. regulator, capacitor, wiring, etc.) and mention the fault condition (e.g. disconnected, short-circuited, etc.). Mention creepage-distances separately if applicable (refer to the text of 52.5 above 52.5.1 in the 601-1 standard)		**N**
52.5.10 b 2	Mention for example safety hazards according to 3.1 and 13 and 52.4		**N**

52.5.9	**FAULT CONDITION TESTS**		**P**

Rated Voltage(V): 100-240V AC

Fuse Rating: 1A

No	Comp. No	Fault	Test voltage (V)	Test time	Fuse No	Fuse current (A)	Mains power/temperatures/results
1	Ventilation opening	Blocked	264	1 hr 45min	Fuse in Inlet	0.13	*Normal operated.* *Temperaturer stabilized.* *See table of 42* *No hazard.*
2	Printer motor	Locked	264	30 min	Fuse in Inlet	0.14	Temperature stabilized at 50.2 ° C with ambient 24.2 ° C. No hazard

F No = Fault Number, S-c = Short-circuit, Dis = Disconnection

53	**ENVIRONMENTAL TESTS**		
		See Sub-clause 4.10 and Clause 10.	

54	**CONSTRUCTIONAL REQUIREMENTS - GENERAL**		
		See Clause 55 to 59.	

55	**ENCLOSURES AND COVERS**		
		See Clause 16, 21 and 24.	

56	COMPONENTS AND GENERAL ASSEMBLY - LIST OF CRITICAL COMPONENT PARTS

Part No	Component/ Object	Manufacturer	Type / Model	Ratings / Technical Data	Complies with the following standard	Approved by
	AC/DC Adaptor	Ault Inc.	MW160	Input: 100-240 Vac, 1.2A, 50/60 Hz Output: 12 Vdc, 3.5 A	EN 60601-1	TÜV Rhl.
	Appliance Inlet	Jackson Electronics Inc. Corp	JR-101	10A, 250V	IEC 60320	VDE
	Fuse in AC inlet	ORISEL Co., Ltd.	50T	1A, 250Vac	EN60127-1	VDE
	Mains Connector	SUNG JIN IND. CO	SJS-51	7/10A, 250Vac	IEC 60320	SEMKO
	Mains Cord	Hwajin KDK Co. Ltd	H05VV-F	3G x 0.75mm²	-	SEMKO
	Main switch	ITT Industries Rudolf Schadow GmbH	Serie NE18	6A, 250Vac	EN61058-1	VDE
	DC Motor	Nippon Pulse	PF42-48B1G	DC24V	EN60601-1	Tested in appl.
	PCB	Various	Various	V-1 or better	-	UL
	Enclosure	LG chemical	AF-302	V-0	-	UL
Applied part						
	DOP probe	Bionics Co., Ltd.	Bionics-probe(D)	Max. 5V	EN 60601-1	Tested in appl.
	UC probe	Bionics Co., Ltd.	Bionics-probe(U)	Max. 5V	EN 60601-1	Tested in appl.
	Event Mark jack	Bionics Co., Ltd.	Bionics-probe(U)	Max. 5V	EN 60601-1	Tested in appl.

56.1	**General**	Marking of components (refer to Table in Clause 56).	
56.1 b	Component markings are according with conditions of use	*The components are used according to their ratings. All components in the mains part and applied part are marked or otherwise identified regarding their ratings.*	**P**
56.1 d	Fixing of components.	*The movement of components is prevented.*	**P**
56.1 f	Fixing of wiring.	*Conductors and connectors are adequately secured and insulated. Accidental detachment does not result in a safety hazard.*	**P**
56.3	**Connections - general**		
56.3 a	Incorrect interconnection of accessible connectors is prevented where a hazard may be caused	*No such a connector*	**N**
	Accessible parts are separated from live parts (see 17 g)		**P**
	Plugs for connection of patient circuit cannot be connected to other outlets		**P**
	Medical gas connections are not interchangeable (see Sub-clause 6.6 and ISO R407)	*Not applicable.*	**N**
56.3 b	Accessible conductive parts are prevented from becoming live when connection between different part of the equipment is broken	*Prevented*	**P**
56.3 c	Connectors having conductive connection to patient are constructed so that no conductive connection of the connector remote from patient can contact earth or hazardous voltages	*DOPI, DOPII, UC, and Event Mark jack*	**P**
	Test with flat conductive surface	*Not possible by construction*	**P**
	Test with straight unjointed test finger	*No single-pole connectors*	**N**
	Test if able to be plugged into a mains socket		**N**
56.4	**Connections of capacitors**		
	Capacitors not connected between live parts and non- protectively earthed accessible conductive parts	*CB certified AC/DC Adapter used*	**N**
	Capacitors between the mains part and earthed accessible parts, comply with IEC 60384-14 or equivalent	*No capacitors*	**N**
	The enclosure of capacitors are not secured directly to non-protectively earthed accessible metal parts	*No capacitors.*	**N**
	Capacitors or other spark-suppression devices are not connected between contacts of thermal cut-outs	*Not applicable.*	**N**

56.5	**Protective devices**		
	Protective devices which operate by producing a short circuit which results in operation of an overcurrent protection device in supply mains system not used (see also 59.3)	*CB Certified AC/DC Adapter used*	**N**
56.6	**Temperature and overload control devices**		
56.6 a	Thermal cut-outs which require soldering to reset are not used	*No such thermal cut-outs used*	**N**
	Thermal safety devices are provided to prevent temperature limits being exceeded		**N**
	An independent non-self resetting thermal cut-out is provided where the failure of a thermostat may cause a hazard	*Not applicable.*	**N**
	The operating temperature of the above thermal cut-out is between the upper limit of the first thermostat and the safe limit for the function	*Not applicable.*	**N**
	There is an audible alarm where loss of function could present a safety hazard	*Not applicable.*	**N**
	Test of thermal cut-outs and overcurrent releases	*Not applicable.*	**N**
	Heated liquid containers are protected against dangerous overheating when container is empty	*Not applicable.*	**N**
56.6 b	Means provided for varying the temperature setting of thermostats, the temperature setting is clearly indicated	*Not applicable.*	**N**
	The operating temperature of thermal cut-outs is clearly indicated	*Not applicable.*	**N**
56.7	**Batteries**		
56.7 a 1	Adequately ventilation	*Not applicable.*	**N**
56.7 a 2	Accidental short-circuiting is prevented (Note! Lithium batteries)		**N**
56.7 b	Incorrect polarity of connection prevented (Note! Lithium batteries) 1) Establish whether there is a possibility of making an incorrect battery connection. 2) Where such a possibility exists, establishing the effect of an incorrect battery connection.		**N**
	Type of battery is clearly marked (see also 6.2 d)		**N**
56.7 c	Battery state.	*No general requirement.*	**N**

56.8	**Indicators**		
	Unless indication is otherwise apparent to the operator from normal operating position , indicator lights are provided:	*Colors, see Sub-clause 6.7.*	**P**
	- to indicate that equipment is energised	*See Sub-clause 6.3 a.*	**P**
	- to indicate the operation of non-luminous heaters	*Not applicable.*	**N**
	- to indicate when output exists if a safety hazard could result	*Not applicable.*	**N**
	Charging mode is visibly indicated to the operator	*See Sub-clause 6.7.*	**P**
56.10	**Actuating parts of controls**		
56.10 a	Accessible parts of electrical controls comply with requirements in Sub-clause 16 c		**N**
56.10 b	Fixing, prevention of maladjustments:		**N**
	Actuating parts are adequately secured to prevent them working loose during normal use		**N**
	Controls are secured to prevent movement relative to scale marking		**N**
	Detachable indicating devices are prevented from incorrect connection without the use of a tool		**N**
56.10 c	Stops of adequate mechanical strength are provided on rotating or movable parts of controls, where necessary to prevent an unexpected change from maximum to minimum, or vice-versa, of the controlled parameter where this could produce a safety hazard		**N**
	Manual torque test		**N**
	Axial pull test		**N**
56.11	**Cord connected hand-held and foot-operated control devices**		
56.11 a	Voltages on cord connected control devices do not exceed 25 V a.c. or 60 V d.c. or peak value	*Measured voltage of probes : Max. 5 V*	**P**
	Circuits isolated from mains part (see 17 g)		**P**
56.11 b	Hand-held control devices: No safety hazard as a result of the free fall test (Sub-clause 21.5)		**P**
	Foot-operated control devices able to support the weight of an adult human being. Test with an actuating force of 1350 N over an area of 625 mm^2. No damage to the device resulting in a safety hazard.	*See above*	**N**

56.11 c	Hand-held and foot-operated control devices do not change their control setting when inadvertently placed in abnormal position		**N**
56.11 d	IP-classification of foot-operated control device at least IPX1		**N**
	Electrical switching parts specified for use in operating rooms at least IPX8		**N**
56.11 e	Provided with adequate means of anchoring as for power supply cords (see test of 57.4).		**N**

57	**MAINS PARTS, COMPONENTS AND LAY-OUT**		
57.1	**Isolation from supply mains**		
57.1 a	Means of isolation:	*Approved AC inlet*	**P**
	The equipment has means for simultaneous disconnection of all supply poles	*See above*	**P**
	Means for disconnection incorporated in equipment	*See above*	**P**
	External means for disconnection are specified in accompanying documents		**N**
57.1 d	Switches for mains disconnection comply with creepage distance and air clearances (IEC 60328 , replaced by IEC 60 61058-1)	*VDE Certified by IEC61058-1*	**P**
57.1 f	Mains switches are not incorporated in power supply cord or flexible leads		**P**
57.1 g	The directions of movement of actuators of mains switches comply with IEC 60447	*"I/O" marked*	**P**
57.1 h	Suitable plug device used to isolate the non-permanently installed equipment from the supply mains		**N**
57.1 m	Fuses and semiconductor devices are not used as isolating devices		**N**
57.2	**Mains connectors , appliance inlets and the like**		
57.2 e	Auxiliary mains sockets outlets:	*No Auxiliary mains sockets outlets*	**N**
	- cannot accept a mains plug (does not apply to emergency trolleys)		**N**
	Number of socket-outlets on emergency trolleys are limited to maximum 4.		**N**
	- and they are properly marked		**N**

57.3	**Power supply cords**		
57.3 a	Equipment not provided with more than one connection to supply mains	*One connection to supply mains*	**P**
	Alternative connections to a different supply system do not cause safety hazards when more than one connection is made simultaneously	*Not applicable.*	**N**
	Mains plug not fitted with more than one power supply cord	*One power supply cord*	**P**
	Equipment not intended to be permanently connected to fixed wiring is provided with either a power supply cord or an appliance inlet	*Appliance inlet.*	**P**
57.3 b	Power supply cords not less robust than ordinary flexible cord, designation 53 of IEC 60245 or IEC 60227		**P**
	PVC insulated power supply cords not used for equipment having external metal parts exceeding 75°C , unless cord rated for the temperature measured		**P**
57.3 c	Cross-sectional area of power supply cords (see Table XV)	*3 x 0.75 mm²*	**P**
57.3 d	Stranded conductors fixed by any clamping means or screws are not soldered	*Detachable power cord set used.*	**N**

57.4	**Connection of Power Supply Cords**		
57.4 a	Cords anchorages:	*Probes*	**P**
	The equipment or its mains connectors incorporate a cable anchoring device to relieve strain on conductors and prevent abrasion of covering (no knots etc.)		**P**
	The construction and materials of the cord anchorages are made of insulating material or insulated from unearthed accessible metal parts by supplementary insulation,		**P**
	or having an insulating lining complying with the requirements for basic insulation fixed to the cord anchorage if an insulation fault on power supply cord could make accessible parts live		**P**
	Clamping screws do not bear directly on the cord insulation		**P**
	Screws associated with cable replacement are not used to fix other components		**P**
	Conductors so arranged that if the cord anchorage fails no strain on protective earth conductor occurs as long as phase conductors are in contact with their terminals	*Not applicable*	**N**
	Pull test 25 times	*At 30N for probes*	**P**
	Torque test for 1 min	*With 0.1Nm for probes*	**P**
	After the tests, the cord sheath has not been longitudinally displaced by more than 2 mm and the conductor ends have not moved over a distance of more than 1 mm from their normally connected position		**P**
	Creepage distances and air clearances are not reduced below the values specified in Sub-clause 57.10.		**P**
	Not possible to push the cord into equipment to such an extent that the cord, or internal parts of the equipment, could be damaged		**P**
57.4 b	For other than stationary equipment, the power supply cord is adequately protected against excessive bending by means of a cord guard of insulating material	*Probes*	**P**
	Alternatively shaped opening for the power supply cord		**P**
	Bending test:	*Overall diameter: 5.0 mm for probes* *Overall diameter: 3.0 mm for probe* *(*Event mark jack*)*	**P**
	Flexing test (if guards fail the dimensional test) (see IEC 60335-1 AM 6:1988, Sub-clause 25.10)		**N**
	Results of flexing test:		**N**
	Percent of broken conductor strands:		**N**

57.4 c	There is sufficient space inside the equipment to allow the supply cable conductors to be introduced and connected		N
	Any covers can be fitted without risk of damage to the conductors or their insulation		—
	It is possible to check that conductors are correctly connected before the cover is fitted		N
57.5	**Mains Terminal Devices and wiring of mains part**		
57.5 a	Mains connected equipment other than those with a detachable supply cord is provided with mains terminals, where connections are made with screws, nuts , soldering , clamping , crimping of conductors or equally effective methods	*Appliance inlet used*	P
	Reliance not placed upon terminals alone to maintain conductors in position, unless barriers are provided	*Not applicable.*	N
	Terminals of components used for external conductors comply with specified requirements and are properly marked (see 6.2 h, j and k)	*Not applicable.*	N
	Screws and nuts which clamp external conductors are not used to fix any other component (other than internal conductors unlikely to be displaced)		N
	Barriers provided		N
57.5 b	Terminals including any protective earth terminal are closely grouped to allow easy connection	*Not applicable.*	N
	Protective earth conductor, see 58	*Not applicable.*	N
	Marking of mains terminals, see 6.2	*Not applicable.*	N
	Mains terminal devices are inaccessible without the use of a tool	*Not applicable.*	N
	Mains terminal devices are so located or shielded that there is no risk of accidental contact between live parts and accessible conductive parts	*No accidental contact possible*	P
	- and for class II equipment between live parts and conductive parts separated from accessible parts by supplementary insulation only		N
	Single strand of wire (8 mm). Test result:		N
57.5 c	Tightening or loosening of clamping means of conductors does not subject internal wiring to stress		N
	- does not reduce creepage distances and air clearances below allowable values		N
	Cross-sectional area of the conductor used in the fastening and loosening test:		N

57.5 d	Effective connection to mains terminals does not require special preparation of cables		**N**
	Conductors are not damaged or displaced when tightening or loosening of clamping screws or nuts		**N**
57.5 e	Fixing of wiring	*See Sub-clause 56.1 f.*	**N**
57.6	**Mains Fuses and Over-current Releases**		
	List of fuses and over-current releases: See table at the beginning of Clause 56 in this TRF	*2 fuses provided in each line*	**P**
	There are fuses or over-current releases in each supply lead for class I equipment and class II equipment having a functional earth according to Sub-clause 18.1		**P**
	There is at least one mains fuse for other single phase class II equipment	*Class I equipment*	**N**
	A protective earth conductor is not fused		**P**
	No fuse is fitted in neutral conductor of permanently installed equipment	*Portable equipment*	**N**
57.8	**Wiring of Mains Part**		
57.8 a	The insulation of an individual conductor is at least equivalent to that required by IEC 60227 or IEC 60245 (otherwise the conductor is considered bare)		**P**
	- dielectric strength test of 2000 V for 1 min	*All wiring of mains part*	**P**
57.8 b	The cross-sectional area of internal wiring between the mains terminal and protective devices is not less than minimum required for the power supply cord. Measured area: (see Sub-clause 57.3 c)	*No wiring because 2 mains fuses are employed in the applied inlet.*	**N**
	The cross-sectional area of other wiring in the mains part and sizes of tracks on printed wiring circuits are sufficient to prevent any fire hazard in case of possible fault currents		**P**
	In case of doubt concerning adequacy of incorporated overcurrent protection connecting test performed. No safety hazard arises		**P**
57.9	**Mains supply transformers** (refer to table below)		
57.9.1	Insulation of mains supply transformers protected against overheating in event of short-circuit or overload (see 57.9.1 a and b)	*Not applicable. Approved adapter used*	**N**
	External protective devices connected such that failure of components cannot render the protective devices inoperative		**N**

57.9.1 a	Short-circuit test(s) at 90 to 110 percent of rated supply voltage / voltage range	*Not applicable*	**N**
57.9.1 b	Overload		
	Tests under the conditions specified in Clause 42 until steady thermal conditions are obtained. Results: See table below.	*Not applicable*	**N**
	Loading of a section or winding of the transformer:		**N**
57.9.2	Dielectric strength of electrical insulation between turns and layers		
	Insulation between turns and layers, test performed according to 57.9.2:		**N**
	Voltage used in test:		
	Frequency used in test:		
57.9.4	Construction		
57.9.4 a	One of the following methods is used to separate primary from secondary and patient connected windings:	*Not applicable.*	**N**
57.9.4 c	Means are provided to prevent displacement of end turns	*Not applicable.*	**N**
57.9.4 d	An earthed screen has a minimum overlap of 3 mm and a width at least equal to the axial length of the primary winding	*Not applicable. No earthed screen used.*	**N**
57.9.4 e	The insulation between the primary and secondary winding in reinforced or double insulated transformers consists of:	*Not applicable*	**N**
	number of insulation layer(s):		**N**
	total thickness		**N**
	combination of two layers withstands dielectric strength test for reinforced insulation		**N**
57.9.4 f	The creepage distances between the primary and secondary windings comply with requirements for reinforced insulation, with specified allowances		**N**
	mm at location:		**N**
57.9.4 g	For toroidal transformers:		
	the exit of wires from internal windings is provided with double sleeving complying with requirements for double insulation	*Not applicable*	**N**
	its total thickness is at least 0.3 mm extending at least 20 mm outside the winding. Measured thickness:		**N**

57.10	**Creepage distances and air clearance**		
57.10 a	Values (refer to table)		
	Creepage distances and air clearances comply at least with the values of Table XVI		**P**
	Creepage distances for slot insulation of motors are at least 50% of the values in the table with a minimum of 2 mm at 250 V	*Not applicable*	**N**
	Creepage distances and air clearances between defibrillation proof applied parts and other parts are not less than 4 mm	*No defibrillation proof applied parts*	**N**

	Insulation between	Ref. voltage (V)	Air clearance (mm)		Creepage distance (mm)		Notes
			Required	Measured	Required	Measured	
Equivalent to Basic insulation between parts of opposite polarity	A -f	*250*	*1.6*	*>1.6*	*3.0*	*>3,0*	*Before fuse*
Equivalent to Basic insulation between parts of opposite polarity	A -f	*12*	*0.4*	*2.6*	*0.8*	*2.6*	*DC Input*
Basic or supplementary insulation	A – a1	*250*	*2.5*	*4.0*	*4.0*	*4.0*	*AC/DC Adapter*
Basic or supplementary insulation	A – a1	*250*	*2.5*	*5.0*	*4.0*	*5.0*	*AC inlet*
Double insulation or reinforced insulation	A – a2	*250*	*5.0*	*>5.0*	*8.0*	*>8.0*	*AC/DC Adapter*
Double insulation or reinforced insulation	A - e	*250*	*5.0*	*5.0*	*8.0*	*10.0*	*AC/DC Adapter*
Double insulation or reinforced insulation	B-a	*250*	*5.0*	*5.0*	*8.0*	*10.0*	*Probe*

Comments		
57.10 b	Statements , test specifications etc. observed	
57.10 d	Statements regarding measurement of creepage distances and clearances observed	

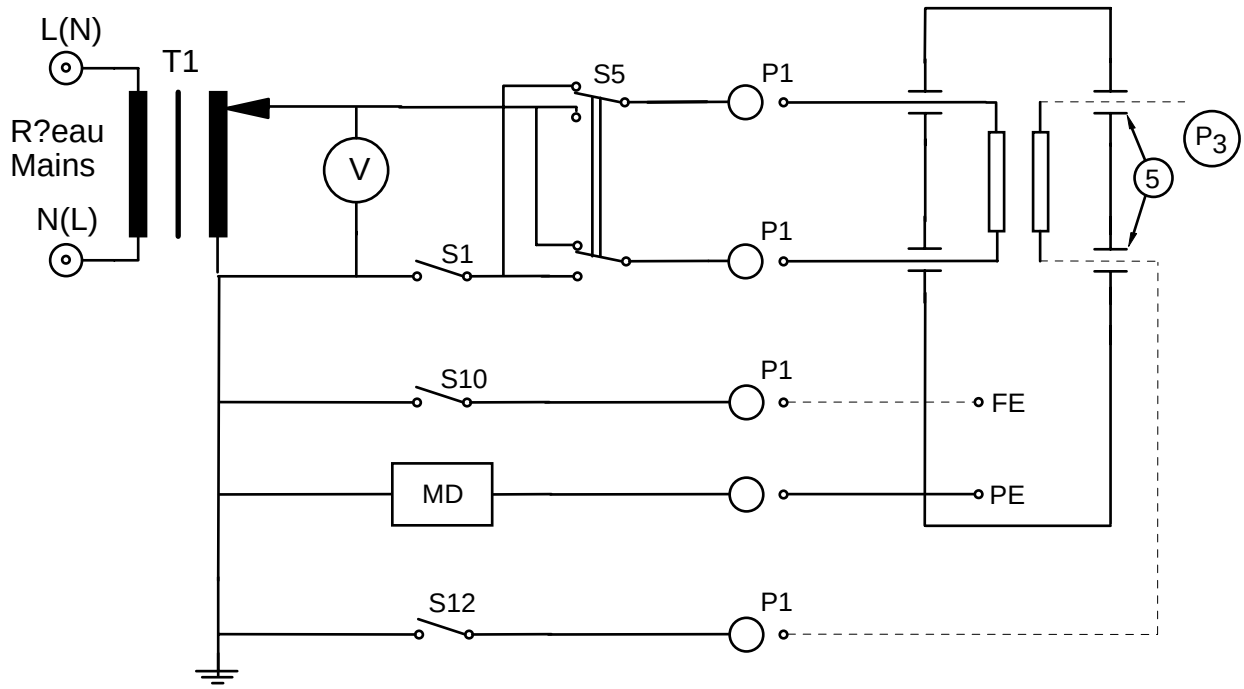
58	PROTECTIVE EARTHING -TERMINALS AND CONNECTIONS		
58.1	Clamping means of the protective earth terminal for fixed supply conductors or power supply cords comply with requirements of Sub-clause 57.5 c:	*Detachable power supply cord used*	**N**
	Not possible to loosen the clamping means without use of a tool	*Not applicable.*	**N**
	Screws for internal protective earth connections are covered or protected against loosening from outside	*Not applicable.*	**N**
58.2	Internal protective earthing connections by means of screw, soldering, crimping, wrapping, welding or a reliable pressure contact		**P**
58.3	Not used (see 57.5 b)		
58.7	Where an appliance inlet is used for the supply connection, its earth pin is regarded as the protective earth terminal		**P**
58.8	The protective earth terminal is not used for connection between different parts or fixing of any component not related to protective or functional earthing		**P**
58.9	Where the protective earth connections are made via a plug or socket device the protective earth connection is made before and interrupted after the supply connections during connection and interrupting	*Connected together with appliance inlets of equipment and integral part of AC/DC adaptor*	**P**

59	CONSTRUCTION AND LAYOUT		
59.1	**Internal wiring**		
	Fixing of wiring in the applied part and the mains part, see Sub-clause 56.1 f		**P**
59.1 a	Internal cables and wiring:		
	- are protected against contact with moving parts and friction with sharp corners and edges	*The wiring is adequately protected against sharp edges, moving parts and etc.*	**P**
	- are protected by additional fixed sleeving or similar means , if there is movement relative to metal parts where it is in direct contact with metal parts	*Not applicable.*	**N**
	- and wiring , cord forms or components are not likely to be damaged by opening or assembling the equipment or opening or closing of inspection doors		**P**

59.1 b	The bending radius of cables and cable forms is at least 5 times the outer diameter of the lead	*Not applicable.*	**N**
59.1 c	Insulation:		
	- insulating sleeving is adequately secured. It can only be removed by breaking or cutting or is secured at both ends	*Tubings for AC inlet terminals*	**P**
	Sheath of a flexible cord used as supplementary insulation inside equipment is not subject to undue mechanical or thermal stresses and its insulation properties are at least as specified in IEC 60227 or IEC 60245	*Not applicable.*	**N**
	- insulated conductors, which are subject to temperatures greater than 70°C, have an insulation of heat-resistant material	*Not applicable.*	**N**
	Dielectric strength test of insulation of 2000 V for 1 min	*Not applicable.*	**N**
59.1 d	Aluminium wires below 16 mm² cross-section are not used	*No aluminium wires*	**N**
59.1 e	Separation of circuits (see Clause 17)		
59.1 f	Connecting cords between equipment parts (e.g. parts of an x-ray or patient monitoring installation or a data-processing installation or combinations) are considered belonging to equipment and subject to requirements of this standard	*Not applicable.*	**N**
59.2	**Insulation**		
59.2 b	Insulation characteristics, mechanical strength and resistance to heat and fire is retained. Result of the ball-pressure test:	*Test of enclosure parts: Temperature of ball 75 °C. Enclosure 1.3 mm*	**P**
59.2 c	Insulation is not likely to be impaired by deposition of dirt or dust resulting from wear of parts within the equipment such that creepage distances and clearances are reduced below specified values		**P**
	Ceramic materials and the like specified in this sub-clause are not used as supplementary or reinforced insulation	*Not applicable.*	**N**
	Rubber materials used as supplementary insulation in class II equipment are resistant to ageing (oxygen test) and arranged and dimensioned adequately		**N**
	Creepage distances are not reduced below values specified in 57.10 despite any cracks in such insulation		**N**

	Insulating materials in which heating elements are embedded are not used as reinforced insulation		**N**
59.3	**Excessive current and voltage protection**		
	See Sub-clause 57.6. An internal electrical power source in equipment is provided with an appropriately rated device to protect against fire hazards. Protective means used. Inspection of design data	*Not applicable.*	**N**
	Fuse elements replaceable without opening the enclosure are fully enclosed in a fuseholder and fuse replacement does not cause safety hazard. Test with standard test finger.	*There were fuse inside of Inlet*	**P**
	Live parts of fuseholders are shielded to prevent electric shock when replacing fuses (if replaceable without the use of a tool)	*There were fuse inside of Inlet*	**P**
	Protective devices between an F-type applied part and the enclosure do not operate below 500 V r.m.s.	*No such a protective device*	**N**
59.4	**Oil containers**		
	Oil containers in portable equipment are adequately sealed to prevent oil loss in any position and the oil container design allows for the expansion of oil	*Not applicable.*	**N**
	Oil containers in mobile equipment are sealed to prevent loss of oil during transport		**N**
	An oil level indicator is provided on partially sealed oil-filled equipment or parts. Inspection of equipment and technical description , and by manual test		**N**

19.4 f	APPENDIX 1		
Fig. 16 in IEC 60601-1	Measurement of the earth leakage current		P



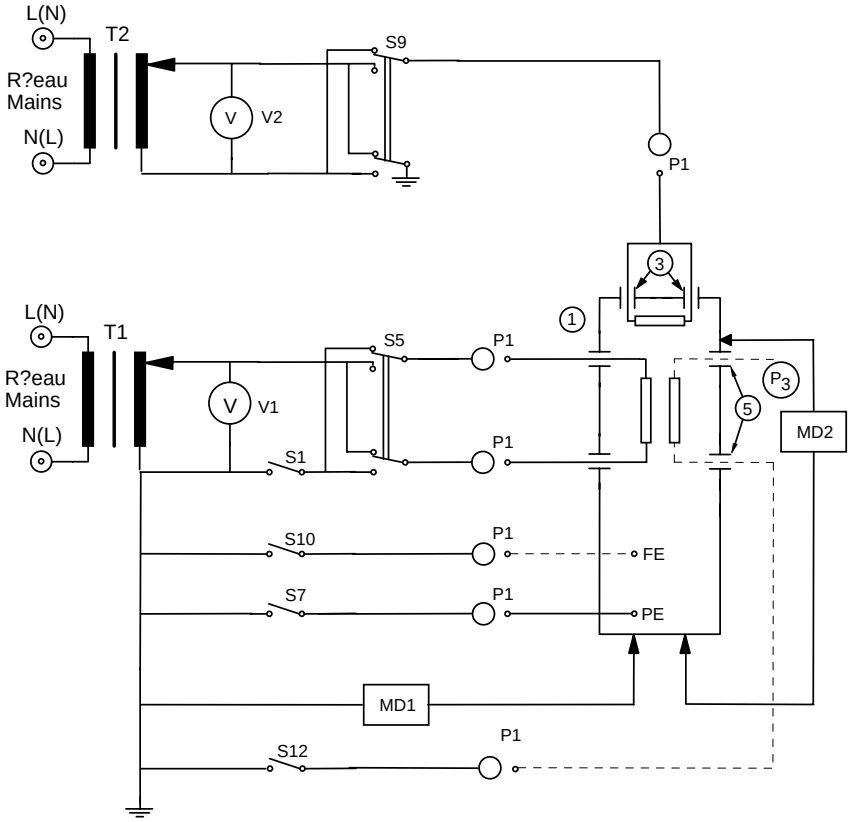
(Measuring supply circuit with one side of the supply mains at approximately earth potential (fig. 10)).

Switch positions		NC (S1 = 1) Measured (µA)		SFC (S1 = 0) Measured (µA)		Additional SFC* (see Clause 17.a)* (S1 = 1) Measured (µA)	
S5	S12	Before[1]	After[2]	Before[1]	After[2]	Before[1]	After[2]
1	1	*246*	*249*	*450*	*456*	—	—
1	0	*245*	*248*	*451*	*457*	—	—
0	1	*238*	*242*	*452*	*458*	—	—
0	0	*239*	*242*	*453*	*459*	—	—

1)Insulation-enclosed
2)Metal enclosed
3)Combination of Insulation- and metal-enclosed and [2] = Before and after humidity preconditioning treatment.

Note:	NC = Normal Conditions SFC = Single Fault Condition	1 = Switch Closed 0 = Switch Open	* = describe additional SFC according to Sub-clause 17 a in notes above

19.4 g	APPENDIX 2		
Fig. 18 in IEC 60601-1	Measurement of the enclosure leakage current	***FOR MAINS OPERATED EQUIPMENT***	**P**

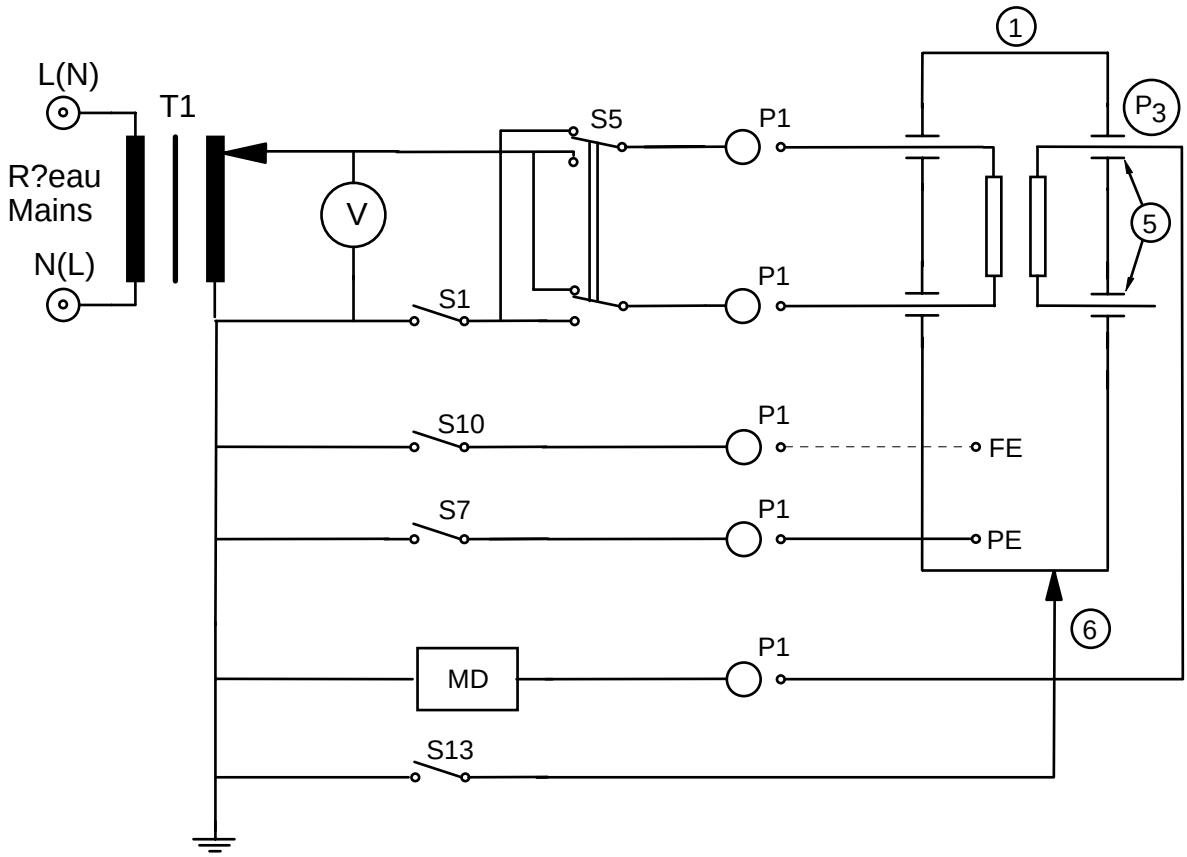


Switch position		NC S1 = 1, S7 = 1 Measured (µA)		SFC S1 = 0, S7 = 1 Measured (µA)		SFC S1 = 1, S7 = 0 Measured (µA)		Additional SFC* S1 = 1, S7 = 1 Measured (µA)	
S5	S12	Before[1]	After[2]	Before[1]	After[2]	Before[1]	After[2]	Before[1]	After[2]
1	1	*56.2*	*56.7*	*55.3*	*56.0*	*56.5*	*56.8*	—	—
1	0	*55.5*	*56.7*	*54.7*	*56.0*	*55.4*	*56.8*	—	—
0	1	*56.4*	*56.7*	*55.2*	*56.0*	*57.3*	*56.8*	—	—
0	0	*56.3*	*56.7*	*54.6*	*56.0*	*56.5*	*56.8*	—	—

[1] and [2] = Before and after humidity preconditioning treatment.

Note:	S7 not used for Class II equipment	NC = Normal Conditions SFC = Single Fault Condition	1 = Switch Closed 0 = Switch Open	* = describe additional SFC according to Sub-clause 17 a in notes above

19.4 h	APPENDIX 3		
Fig. 20 in IEC 60601-1	Measurement of the patient leakage current	***FOR MAINS OPERATED EQUIPMENT (For UC)***	**P**



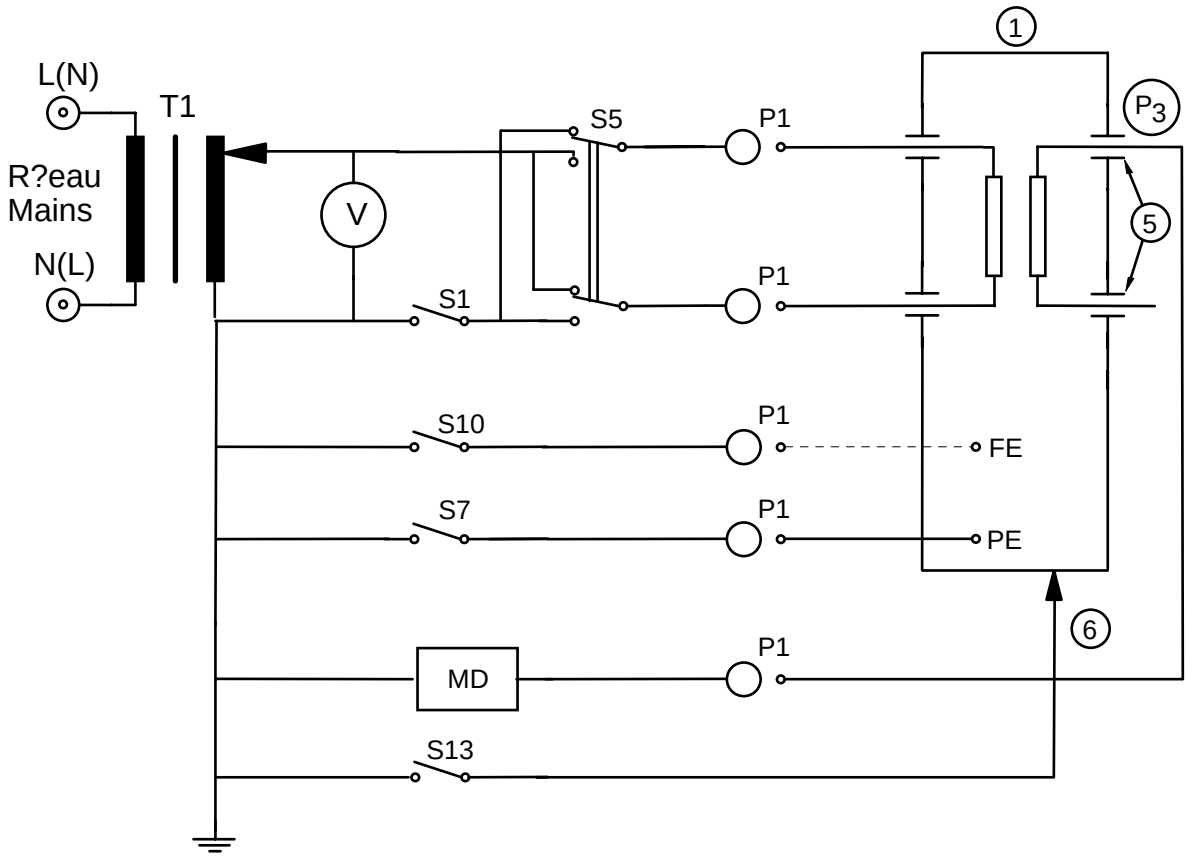
Switch position		NC S1 = 1, S7 = 1 Measured (µA)		SFC S1 = 0, S7 = 1 Measured (µA)		SFC S1 = 1, S7 = 0 Measured (µA)		Additional SFC* S1 = 1, S7 = 1 Measured (µA)	
S5	S13	Before[1]	After[2]	Before[1]	After[2]	Before[1]	After[2]	Before[1]	After[2]
1	1	*55.7 /0.01*	*55.8 /0.01*	*54.5 /0.01*	*55.1 /0.01*	*55.1 /0.01*	*55.6 /0.01*	—	—
1	0	*55.7 /0.01*	*55.8 /0.01*	*54.5 /0.01*	*55.1 /0.01*	*55.1 /0.01*	*55.6 /0.01*	—	—
0	1	*54.3 /0.01*	*55.1 /0.01*	*54.5 /0.01*	*55.1 /0.01*	*55.6 /0.01*	*55.8 /0.01*	—	—
0	0	*54.3 /0.01*	*55.1 /0.01*	*54.5 /0.01*	*55.1 /0.01*	*55.6 /0.01*	*55.8 /0.01*	—	—

[1] and [2] = Before and after humidity preconditioning treatment.

Comments :

Note:	S7 not used for Class II equipment	NC = Normal Conditions SFC = Single Fault Condition	1 = Switch Closed 0 = Switch Open	* = describe additional SFC according to Sub-clause 17 a in notes above ** = AC / DC

19.4 h	APPENDIX 3		
Fig. 20 in IEC 60601-1	Measurement of the patient leakage current	***FOR MAINS OPERATED EQUIPMENT (For DOP I)***	**P**



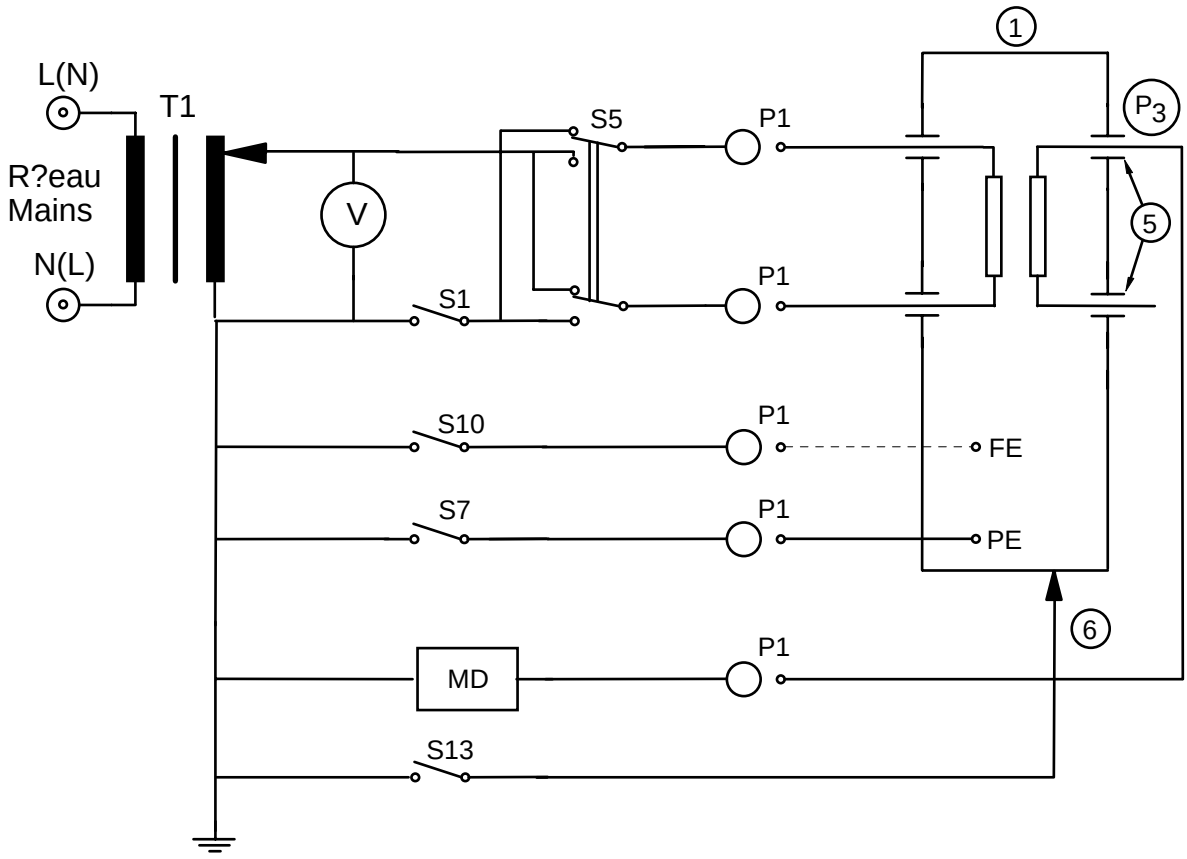
Switch position		NC S1 = 1, S7 = 1 Measured (µA)		SFC S1 = 0, S7 = 1 Measured (µA)		SFC S1 = 1, S7 = 0 Measured (µA)		Additional SFC* S1 = 1, S7 = 1 Measured (µA)	
S5	S13	Before[1]	After[2]	Before[1]	After[2]	Before[1]	After[2]	Before[1]	After[2]
1	1	*55.9 /0.01*	*56.0 /0.01*	*56.1 /0.01*	*56.3 /0.01*	*56.3 /0.01*	*56.5 /0.01*	—	—
1	0	*55.9 /0.01*	*56.0 /0.01*	*56.1 /0.01*	*56.3 /0.01*	*56.3 /0.01*	*56.5 /0.01*	—	—
0	1	*56.3 /0.01*	*56.0 /0.01*	*56.0 /0.01*	*56.3 /0.01*	*56.5 /0.01*	*56.7 /0.01*	—	—
0	0	*56.3 /0.01*	*56.0 /0.01*	*56.0 /0.01*	*56.3 /0.01*	*56.5 /0.01*	*56.7 /0.01*	—	—

[1] and [2] = Before and after humidity preconditioning treatment.

Comments :

Note:	S7 not used for Class II equipment	NC = Normal Conditions SFC = Single Fault Condition	1 = Switch Closed 0 = Switch Open	* = describe additional SFC according to Sub-clause 17 a in notes above ** = AC / DC

19.4 h	APPENDIX 3		
Fig. 20 in IEC 60601-1	Measurement of the patient leakage current	***FOR MAINS OPERATED EQUIPMENT (For DOP II)***	**P**



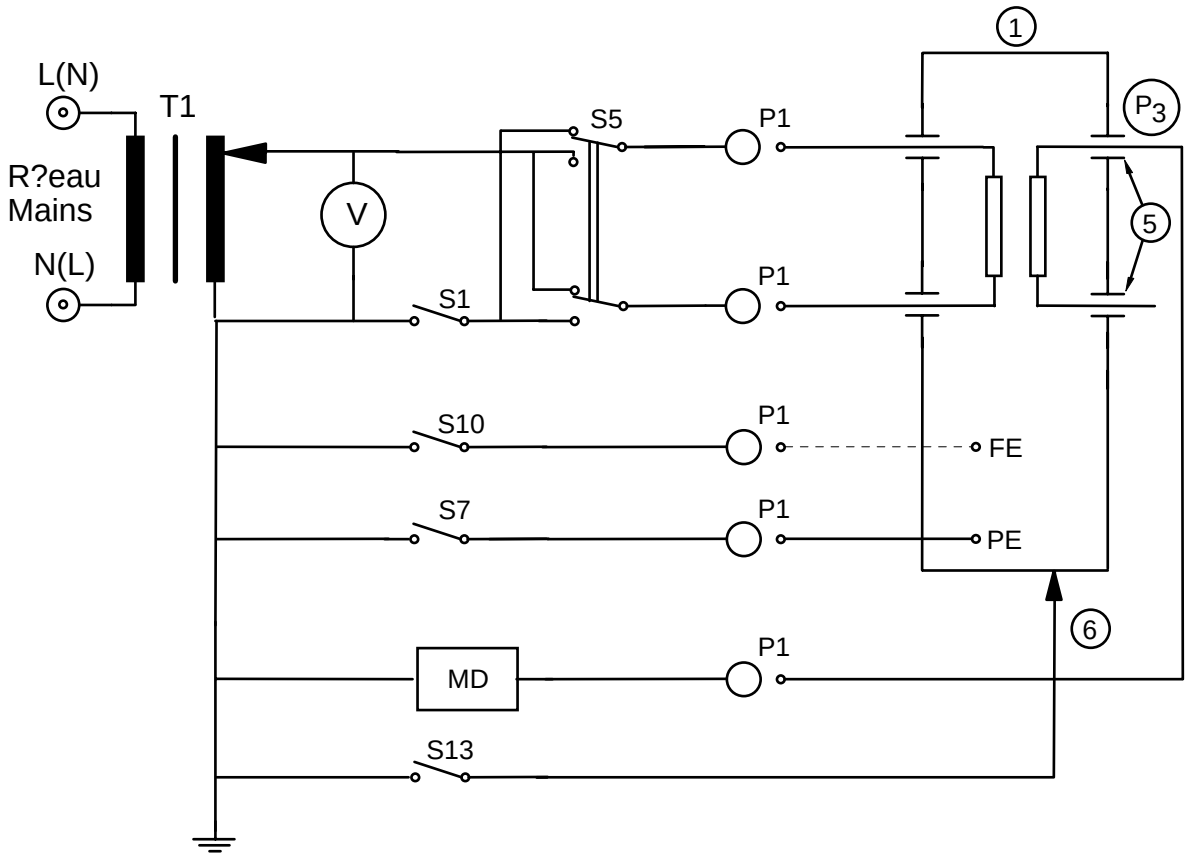
Switch position		NC S1 = 1, S7 = 1 Measured (µA)		SFC S1 = 0, S7 = 1 Measured (µA)		SFC S1 = 1, S7 = 0 Measured (µA)		Additional SFC* S1 = 1, S7 = 1 Measured (µA)	
S5	S13	Before[1]	After[2]	Before[1]	After[2]	Before[1]	After[2]	Before[1]	After[2]
1	1	*56.4 /0.01*	*56.6 /0.01*	*58.7 /0.01*	*58.9 /0.01*	*59.3 /0.01*	*59.5 /0.01*	—	—
1	0	*56.4 /0.01*	*56.6 /0.01*	*58.7 /0.01*	*58.9 /0.01*	*59.3 /0.01*	*59.5 /0.01*	—	—
0	1	*58.7 /0.01*	*58.9 /0.01*	*58.8 /0.01*	*59.0 /0.01*	*58.8 /0.01*	*59.0 /0.01*	—	—
0	0	*58.7 /0.01*	*58.9 /0.01*	*58.8 /0.01*	*59.0 /0.01*	*58.8 /0.01*	*59.0 /0.01*	—	—

[1] and [2] = Before and after humidity preconditioning treatment.

Comments :

Note:	S7 not used for Class II equipment	NC = Normal Conditions SFC = Single Fault Condition	1 = Switch Closed 0 = Switch Open	* = describe additional SFC according to Sub-clause 17 a in notes above ** = AC / DC

19.4 h	APPENDIX 3		
Fig. 20 in IEC 60601-1	Measurement of the patient leakage current	***FOR MAINS OPERATED EQUIPMENT (For Event Mark jack)***	**P**



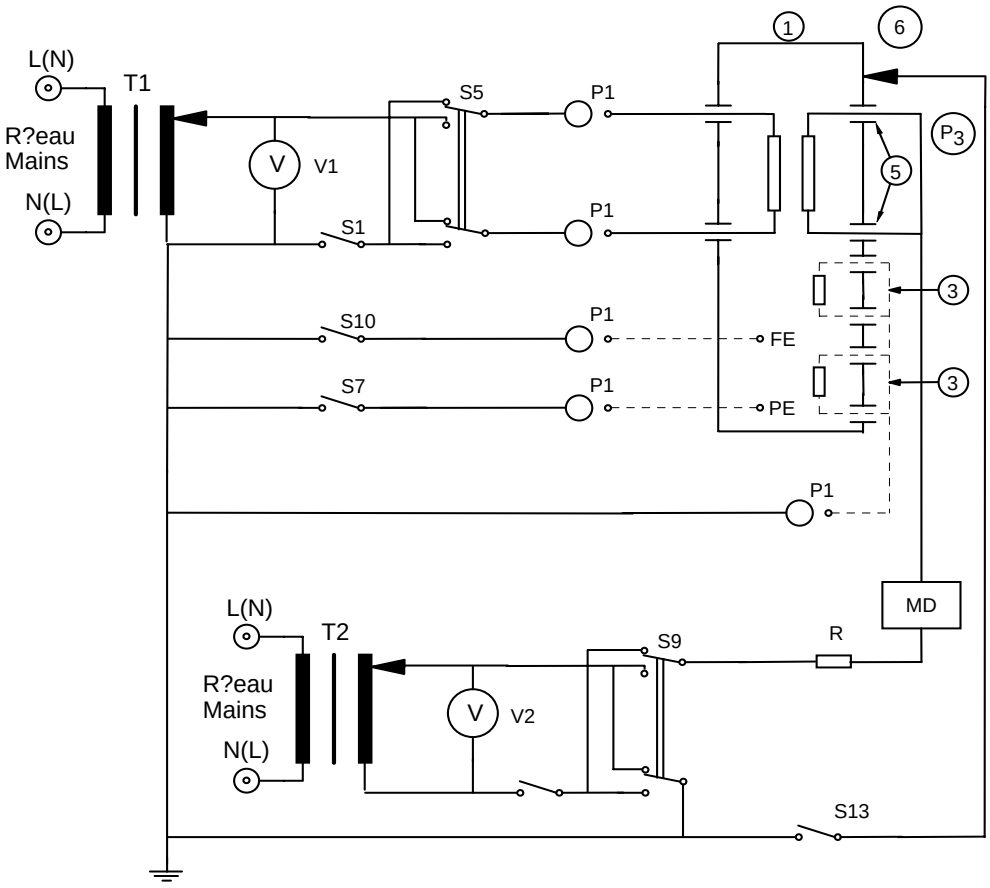
Switch position		NC S1 = 1, S7 = 1 Measured (µA)		SFC S1 = 0, S7 = 1 Measured (µA)		SFC S1 = 1, S7 = 0 Measured (µA)		Additional SFC* S1 = 1, S7 = 1 Measured (µA)	
S5	S13	Before[1]	After[2]	Before[1]	After[2]	Before[1]	After[2]	Before[1]	After[2]
1	1	*56.3 /0.01*	*56.5 /0.01*	*56.1 /0.01*	*56.3 /0.01*	*55.4 /0.01*	*55.6 /0.01*	—	—
1	0	*56.3 /0.01*	*56.5 /0.01*	*56.1 /0.01*	*56.3 /0.01*	*55.4 /0.01*	*55.6 /0.01*	—	—
0	1	*56.2 /0.01*	*56.4 /0.01*	*56.1 /0.01*	*56.3 /0.01*	*55.2 /0.01*	*55.4 /0.01*	—	—
0	0	*56.2 /0.01*	*56.4 /0.01*	*56.1 /0.01*	*56.3 /0.01*	*55.2 /0.01*	*55.4 /0.01*	—	—

[1] and [2] = Before and after humidity preconditioning treatment.

Comments :

Note:	S7 not used for Class II equipment	NC = Normal Conditions SFC = Single Fault Condition	1 = Switch Closed 0 = Switch Open	* = describe additional SFC according to Sub-clause 17 a in notes above ** = AC / DC

19.4 h2	APPENDIX 4		
Fig. 21 in IEC 60601-1	Measurement of the patient leakage current with mains voltage on the f-type isolated (floating) applied part	***FOR MAINS OPERATED EQUIPMENT (For UC)***	**P**

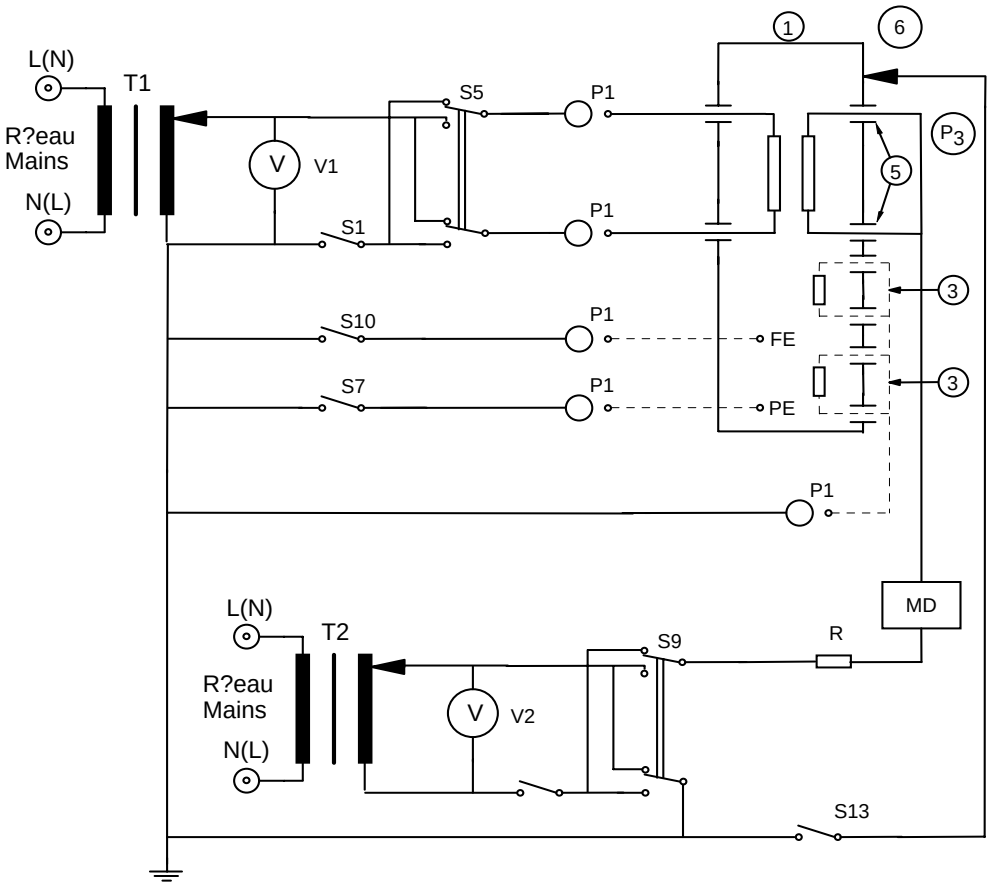


Switch position			Measured µA	
S5	S9	S13	Before[1]	After[2]
1	1	1	*45.7*	*46.0*
1	1	0	*45.7*	*46.0*
1	0	1	*45.4*	*45.7*
1	0	0	*45.4*	*45.7*
0	1	1	*45.7*	*46.0*
0	1	0	*45.7*	*46.0*
0	0	1	*45.4*	*45.7*
0	0	0	*45.4*	*45.7*

[1] and [2] = Before and after humidity preconditioning treatment.

Note:	S7 not used for Class II equipment	NC = Normal Conditions SFC = Single Fault Condition	1 = Switch Closed 0 = Switch Open

19.4 h2	APPENDIX 4		
Fig. 21 in IEC 60601-1	Measurement of the patient leakage current with mains voltage on the f-type isolated (floating) applied part	***FOR MAINS OPERATED EQUIPMENT (For DOP I)***	**P**

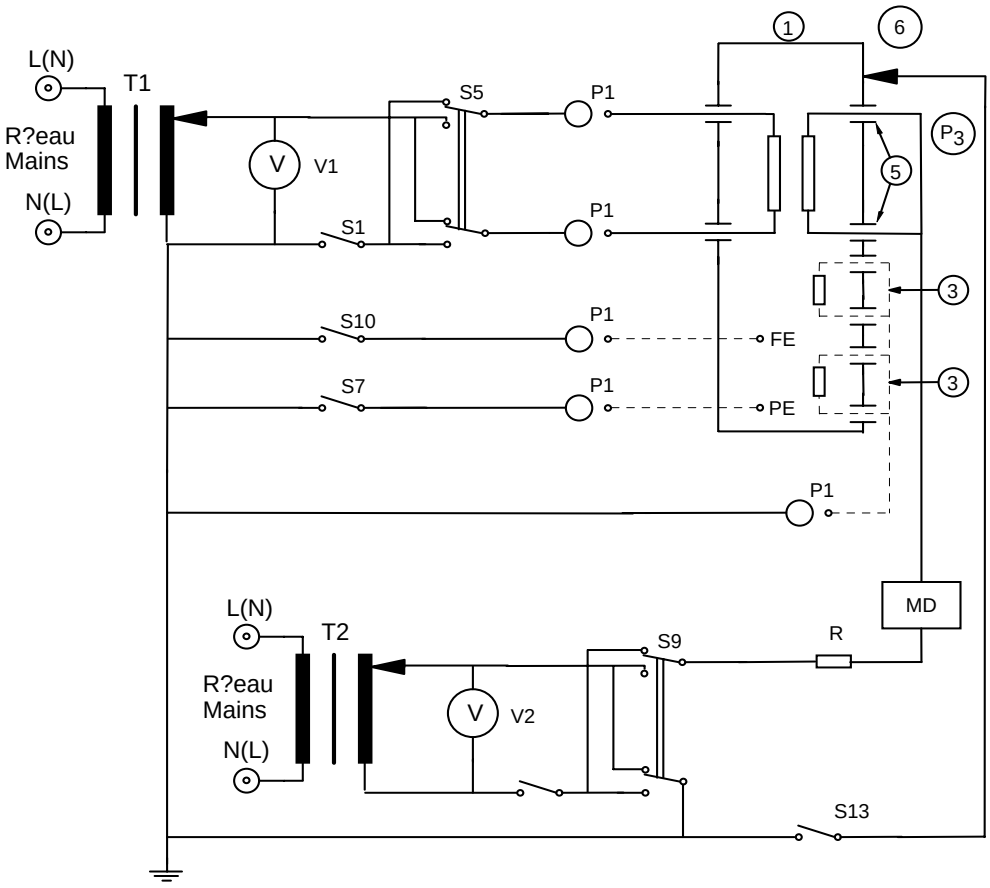


Switch position			Measured µA	
S5	S9	S13	Before[1]	After[2]
1	1	1	*45.0*	*45.3*
1	1	0	*45.0*	*45.3*
1	0	1	*45.9*	*46.2*
1	0	0	*45.9*	*46.2*
0	1	1	*45.1*	*45.4*
0	1	0	*45.1*	*45.4*
0	0	1	*45.8*	*46.1*
0	0	0	*45.9*	*46.1*

[1] and [2] = Before and after humidity preconditioning treatment.

Note:	S7 not used for Class II equipment	NC = Normal Conditions SFC = Single Fault Condition	1 = Switch Closed 0 = Switch Open

19.4 h2	APPENDIX 4		
Fig. 21 in IEC 60601-1	Measurement of the patient leakage current with mains voltage on the f-type isolated (floating) applied part	***FOR MAINS OPERATED EQUIPMENT (For DOP II)***	**P**

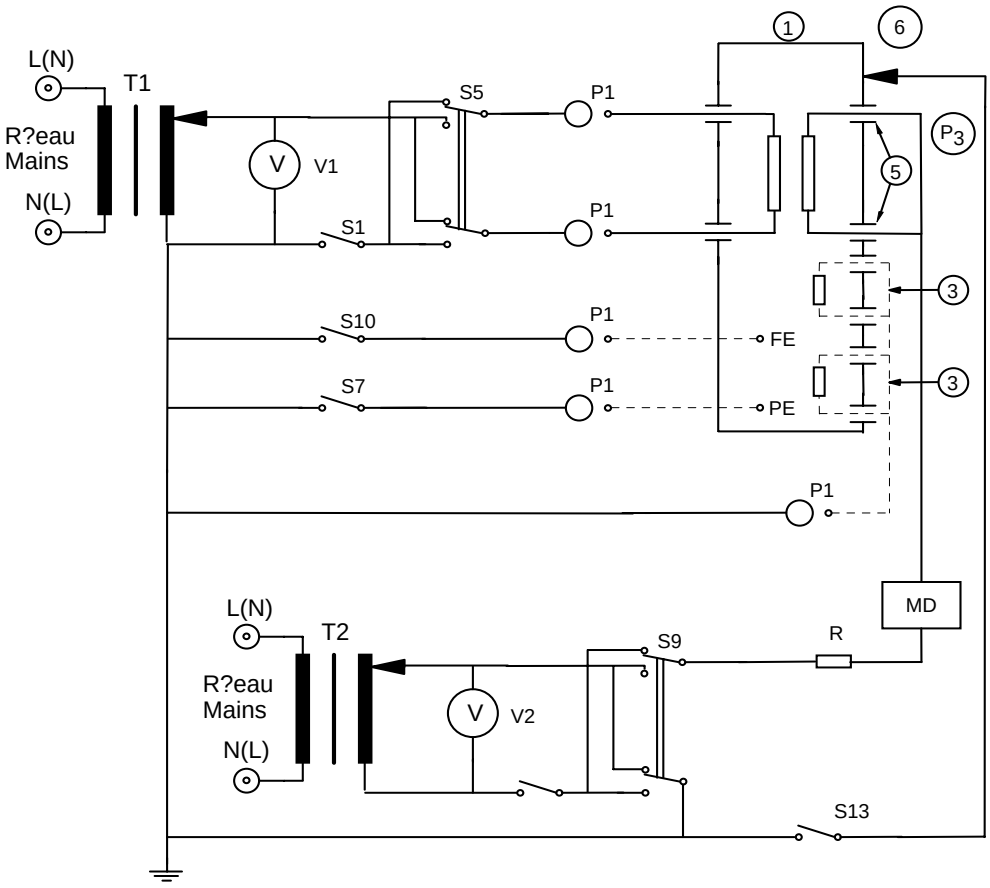


Switch position			Measured µA	
S5	S9	S13	Before[1]	After[2]
1	1	1	*36.8*	*37.1*
1	1	0	*36.8*	*37.1*
1	0	1	*37.4*	*37.7*
1	0	0	*36.7*	*37.0*
0	1	1	*37.5*	*37.8*
0	1	0	*37.4*	*37.7*
0	0	1	*37.3*	*37.6*
0	0	0	*37.3*	*37.6*

[1] and [2] = Before and after humidity preconditioning treatment.

Note:	S7 not used for Class II equipment	NC = Normal Conditions SFC = Single Fault Condition	1 = Switch Closed 0 = Switch Open

19.4 h2	APPENDIX 4		
Fig. 21 in IEC 60601-1	Measurement of the patient leakage current with mains voltage on the f-type isolated (floating) applied part	***FOR MAINS OPERATED EQUIPMENT (For Event Mark jack)***	**P**

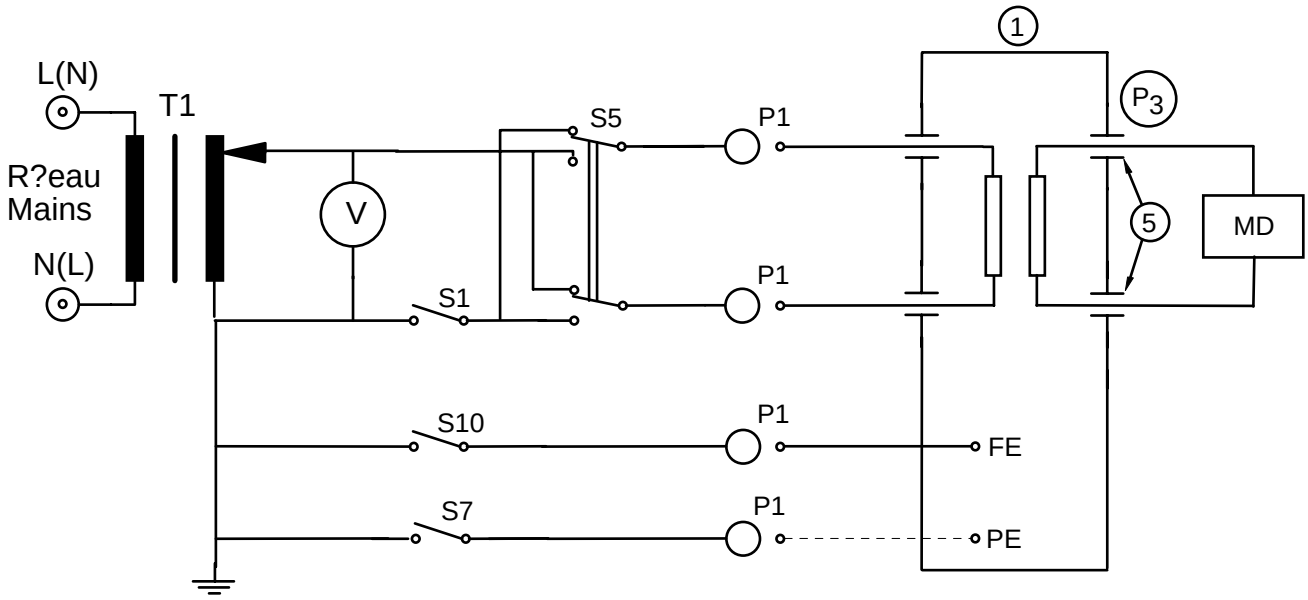


Switch position			Measured µA	
S5	S9	S13	Before[1]	After[2]
1	1	1	*36.4*	*36.7*
1	1	0	*36.4*	*36.7*
1	0	1	*36.7*	*37.0*
1	0	0	*36.7*	*37.0*
0	1	1	*36.4*	*36.7*
0	1	0	*36.4*	*36.7*
0	0	1	*36.7*	*37.0*
0	0	0	*36.7*	*37.0*

[1] and [2] = Before and after humidity preconditioning treatment.

Note:	S7 not used for Class II equipment	NC = Normal Conditions SFC = Single Fault Condition	1 = Switch Closed 0 = Switch Open

19.4 j	APPENDIX 6		
Fig. 26 in IEC 601-1	Measurement of the patient auxiliary current	***FOR MAINS OPERATED EQUIPMENT (Probe: Event Mark jack and DOP II)***	**P**

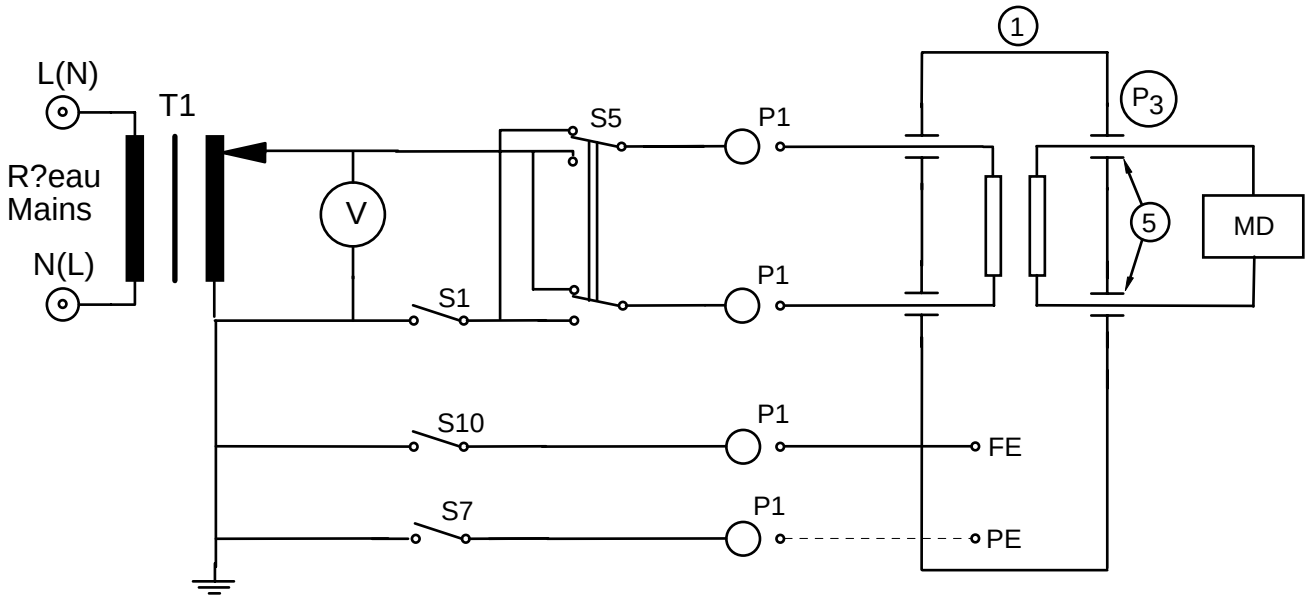


Switch position	NC S1 = 1, S7 = 1 Measured (µA)		SFC S1 = 0, S7 = 1 Measured (µA)		SFC S1 = 1, S7 = 0 Measured (µA)		Additional SFC* S1 = 1, S7 = 1 Measured (µA)	
S5	Before[1]	After[2]	Before[1]	After[2]	Before[1]	After[2]	Before[1]	After[2]
1	*34.6 /0.01*	*34.9 /0.01*	*35.8 /0.01*	*36.1 /0.01*	*38.2 /0.01*	*38.5 /0.01*	—	—
0	*35.1 /0.01*	*35.4 /0.01*	*35.5 /0.01*	*35.8 /0.01*	*38.0 /0.01*	*38.3 /0.01*	—	—

[1] and [2] = Before and after humidity preconditioning treatment.

Note:	S7 not used for Class II equipment	NC = Normal Conditions SFC = Single Fault Condition	1 = Switch Closed 0 = Switch Open	* = describe additional SFC according to Sub-clause 17 a in notes above

19.4 j	APPENDIX 6		
Fig. 26 in IEC 601-1	Measurement of the patient auxiliary current	***FOR MAINS OPERATED EQUIPMENT (Probe: Event Mark jack and UC)***	**P**

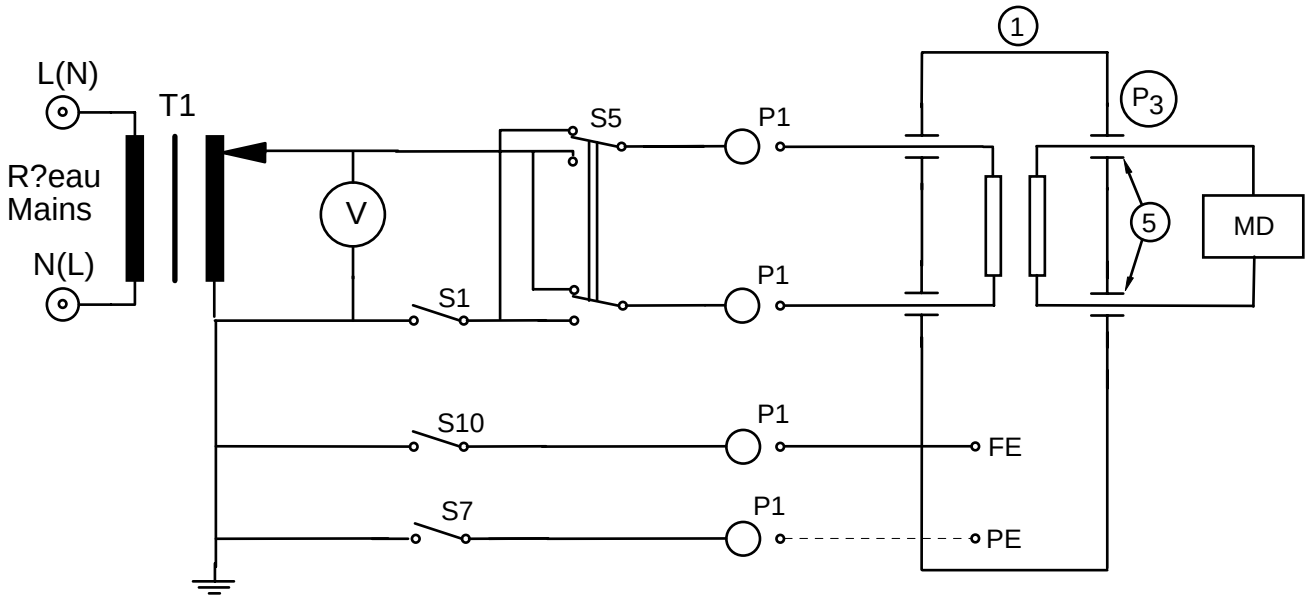


Switch position	NC S1 = 1, S7 = 1 Measured (µA)		SFC S1 = 0, S7 = 1 Measured (µA)		SFC S1 = 1, S7 = 0 Measured (µA)		Additional SFC* S1 = 1, S7 = 1 Measured (µA)	
S5	Before[1]	After[2]	Before[1]	After[2]	Before[1]	After[2]	Before[1]	After[2]
1	*42.1 /0.01*	*42.4 /0.01*	*40.6 /0.01*	*40.9 /0.01*	*47.5 /0.01*	*47.8 /0.01*	—	—
0	*41.1 /0.01*	*41.4 /0.01*	*40.5 /0.01*	*40.8 /0.01*	*47.3 /0.01*	*47.6 /0.01*	—	—

[1] and [2] = Before and after humidity preconditioning treatment.

Note:	S7 not used for Class II equipment	NC = Normal Conditions SFC = Single Fault Condition	1 = Switch Closed 0 = Switch Open	* = describe additional SFC according to Sub-clause 17 a in notes above

19.4 j	APPENDIX 6		
Fig. 26 in IEC 601-1	Measurement of the patient auxiliary current	***FOR MAINS OPERATED EQUIPMENT (Probe: Event Mark jack and DOP I)***	**P**

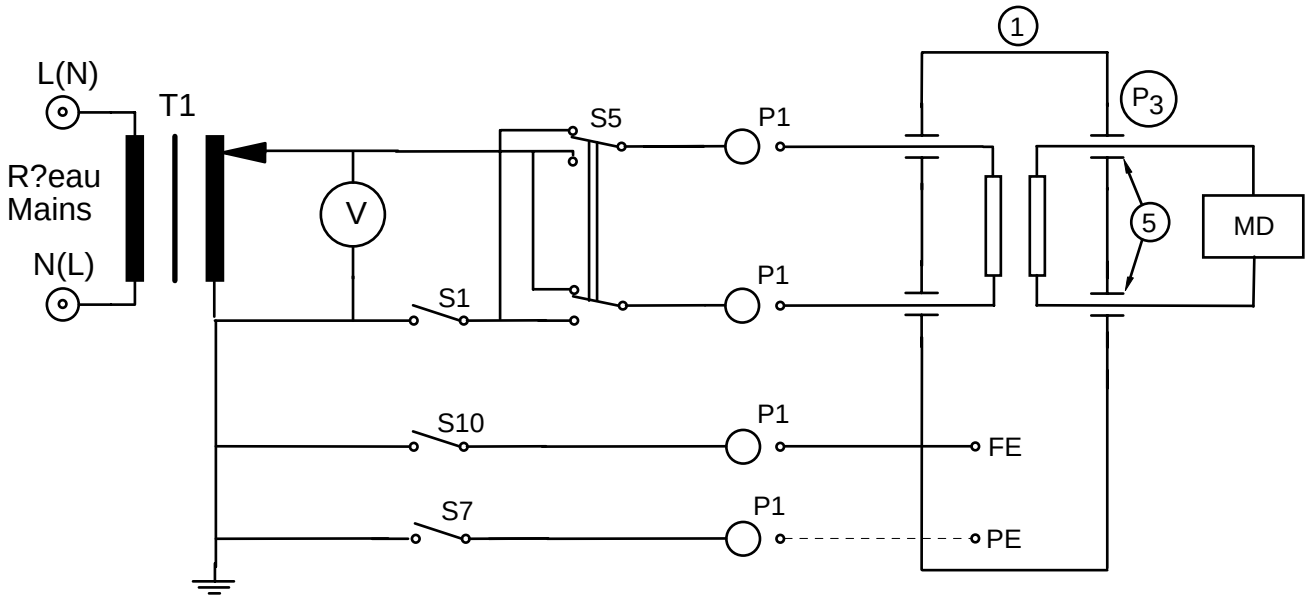


Switch position	NC S1 = 1, S7 = 1 Measured (µA)		SFC S1 = 0, S7 = 1 Measured (µA)		SFC S1 = 1, S7 = 0 Measured (µA)		Additional SFC* S1 = 1, S7 = 1 Measured (µA)	
S5	Before[1]	After[2]	Before[1]	After[2]	Before[1]	After[2]	Before[1]	After[2]
1	*36.8 /0.01*	*37.1 /0.01*	*35.2 /0.01*	*35.5 /0.01*	*36.4 /0.01*	*36.7 /0.01*	—	—
0	*36.7 /0.01*	*37.0 /0.01*	*36.8 /0.01*	*37.1 /0.01*	*37.0 /0.01*	*37.3 /0.01*	—	—

[1] and [2] = Before and after humidity preconditioning treatment.

Note:	S7 not used for Class II equipment	NC = Normal Conditions SFC = Single Fault Condition	1 = Switch Closed 0 = Switch Open	* = describe additional SFC according to Sub-clause 17 a in notes above

19.4 j	APPENDIX 6		
Fig. 26 in IEC 601-1	Measurement of the patient auxiliary current	***FOR MAINS OPERATED EQUIPMENT (Probe: UC and DOP I)***	**P**

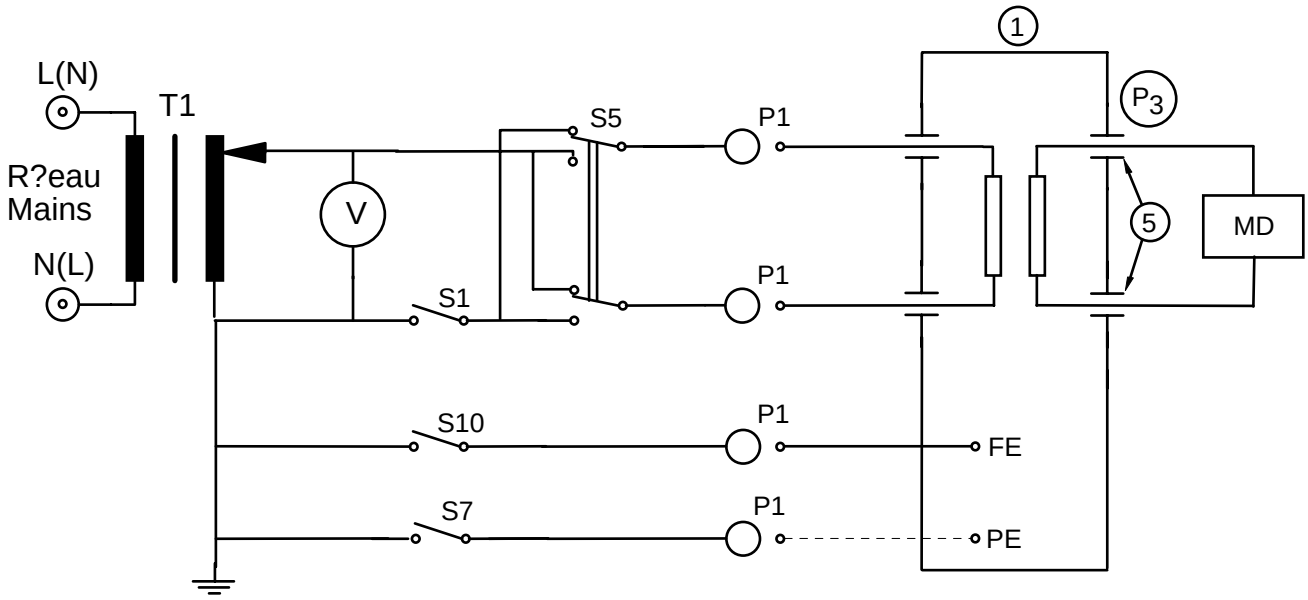


Switch position	NC S1 = 1, S7 = 1 Measured (µA)		SFC S1 = 0, S7 = 1 Measured (µA)		SFC S1 = 1, S7 = 0 Measured (µA)		Additional SFC* S1 = 1, S7 = 1 Measured (µA)	
S5	Before[1]	After[2]	Before[1]	After[2]	Before[1]	After[2]	Before[1]	After[2]
1	*31.9 /0.01*	*32.2 /0.01*	*32.0 /0.01*	*32.3 /0.01*	*34.8 /0.01*	*35.1 /0.01*	—	—
0	*31.5 /0.01*	*31.7 /0.01*	*32.1 /0.01*	*32.3 /0.01*	*34.6 /0.01*	*34.9 /0.01*	—	—

[1] and [2] = Before and after humidity preconditioning treatment.

Note:	S7 not used for Class II equipment	NC = Normal Conditions SFC = Single Fault Condition	1 = Switch Closed 0 = Switch Open	* = describe additional SFC according to Sub-clause 17 a in notes above

19.4 j	APPENDIX 6		
Fig. 26 in IEC 601-1	Measurement of the patient auxiliary current	***FOR MAINS OPERATED EQUIPMENT (Probe: UC and DOP II)***	**P**

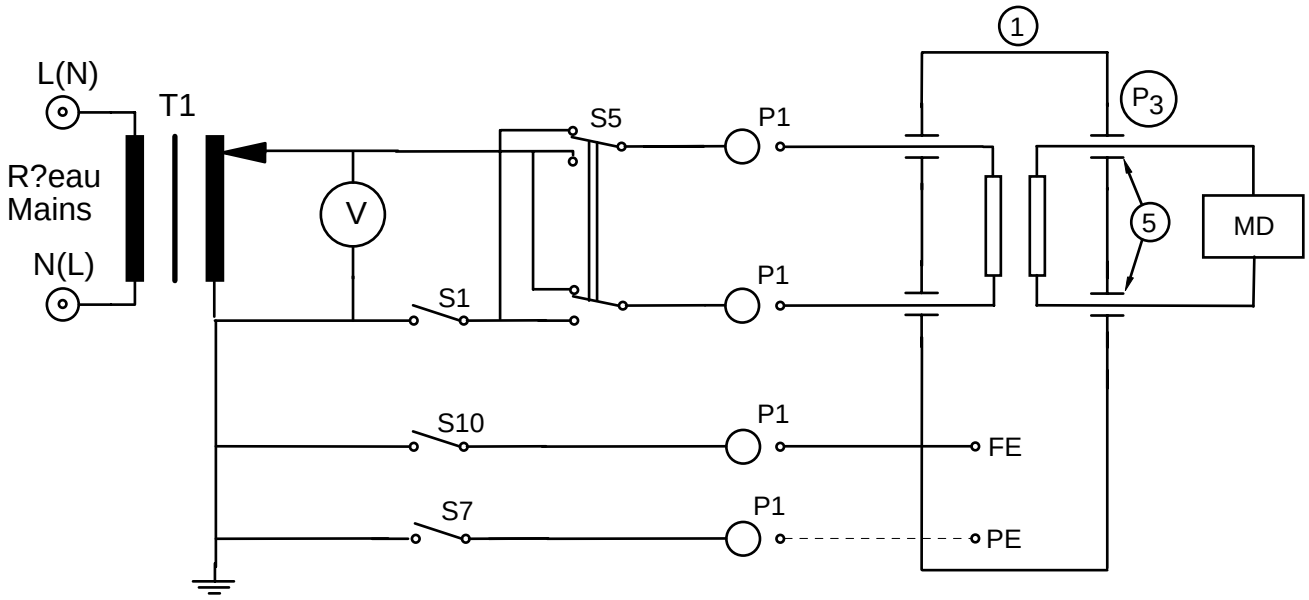


Switch position	NC S1 = 1, S7 = 1 Measured (µA)		SFC S1 = 0, S7 = 1 Measured (µA)		SFC S1 = 1, S7 = 0 Measured (µA)		Additional SFC* S1 = 1, S7 = 1 Measured (µA)	
S5	Before[1]	After[2]	Before[1]	After[2]	Before[1]	After[2]	Before[1]	After[2]
1	*31.5 /0.01*	*31.7 /0.01*	*32.2 /0.01*	*32.5 /0.01*	*34.2 /0.01*	*34.5 /0.01*	—	—
0	*31.8 /0.01*	*32.1 /0.01*	*32.1 /0.01*	*32.4 /0.01*	*34.3 /0.01*	*34.6 /0.01*	—	—

[1] and [2] = Before and after humidity preconditioning treatment.

Note:	S7 not used for Class II equipment	NC = Normal Conditions SFC = Single Fault Condition	1 = Switch Closed 0 = Switch Open	* = describe additional SFC according to Sub-clause 17 a in notes above

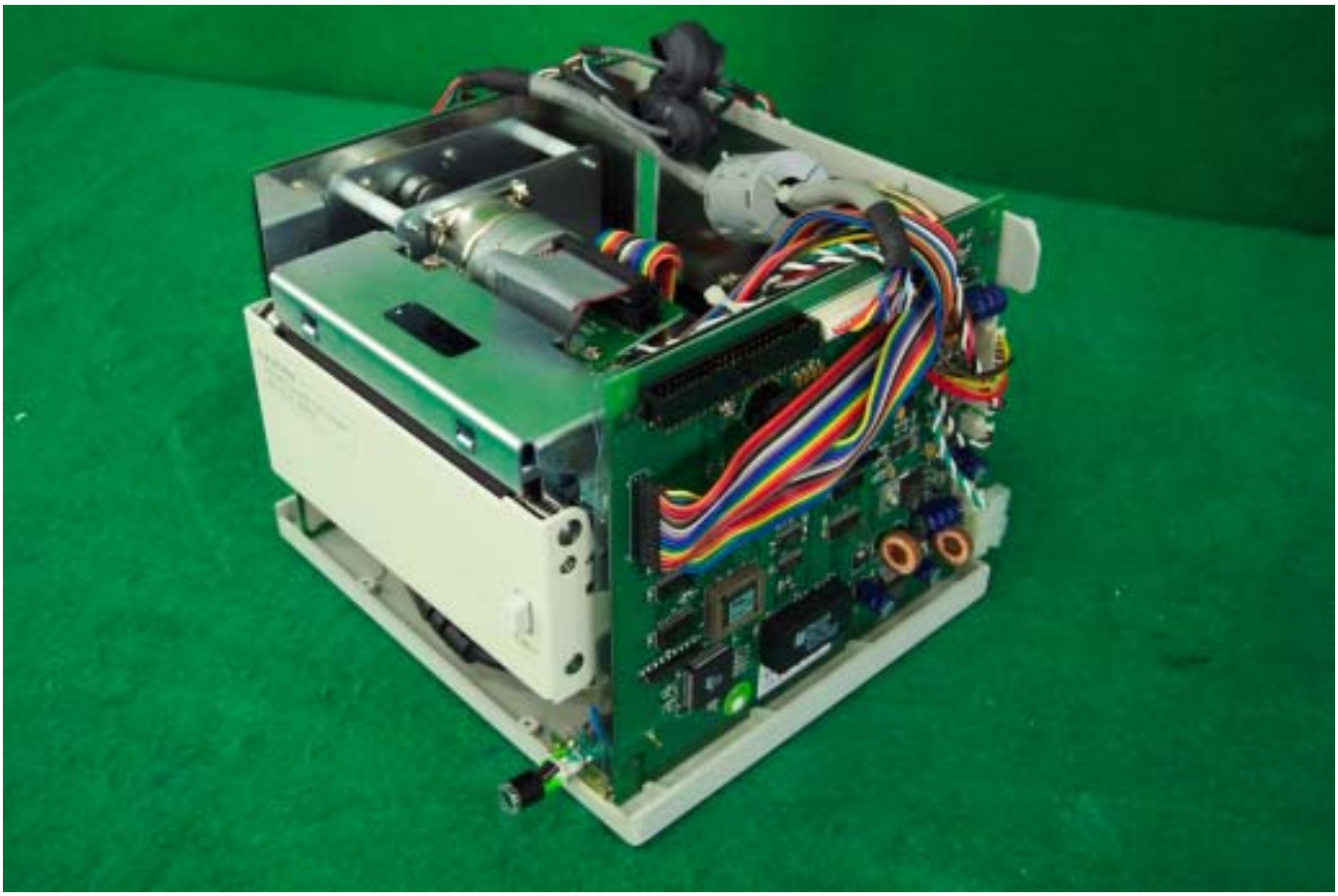
19.4 j	APPENDIX 6		
Fig. 26 in IEC 601-1	Measurement of the patient auxiliary current	***FOR MAINS OPERATED EQUIPMENT (Probe: DOP I and DOP II)***	**P**

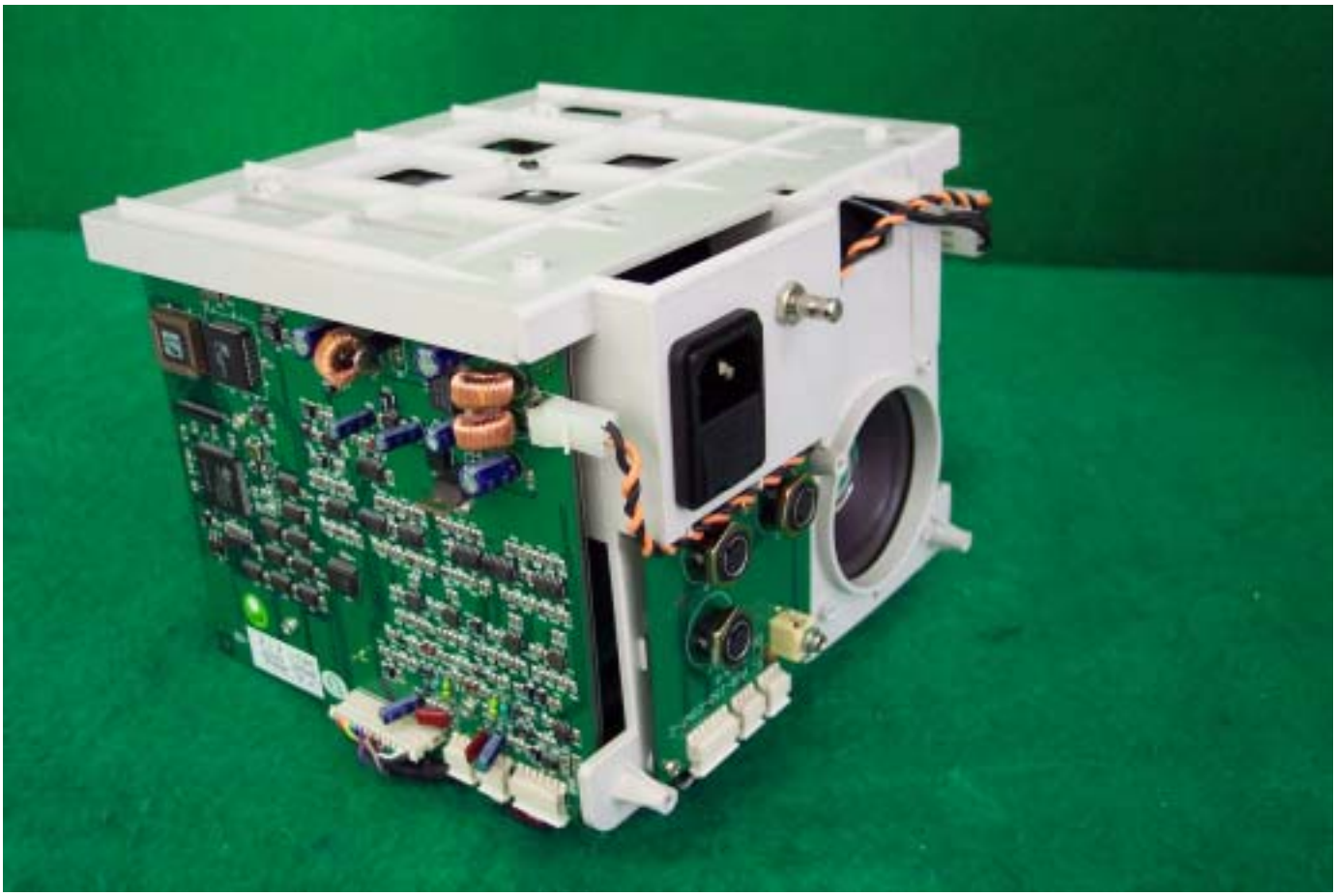


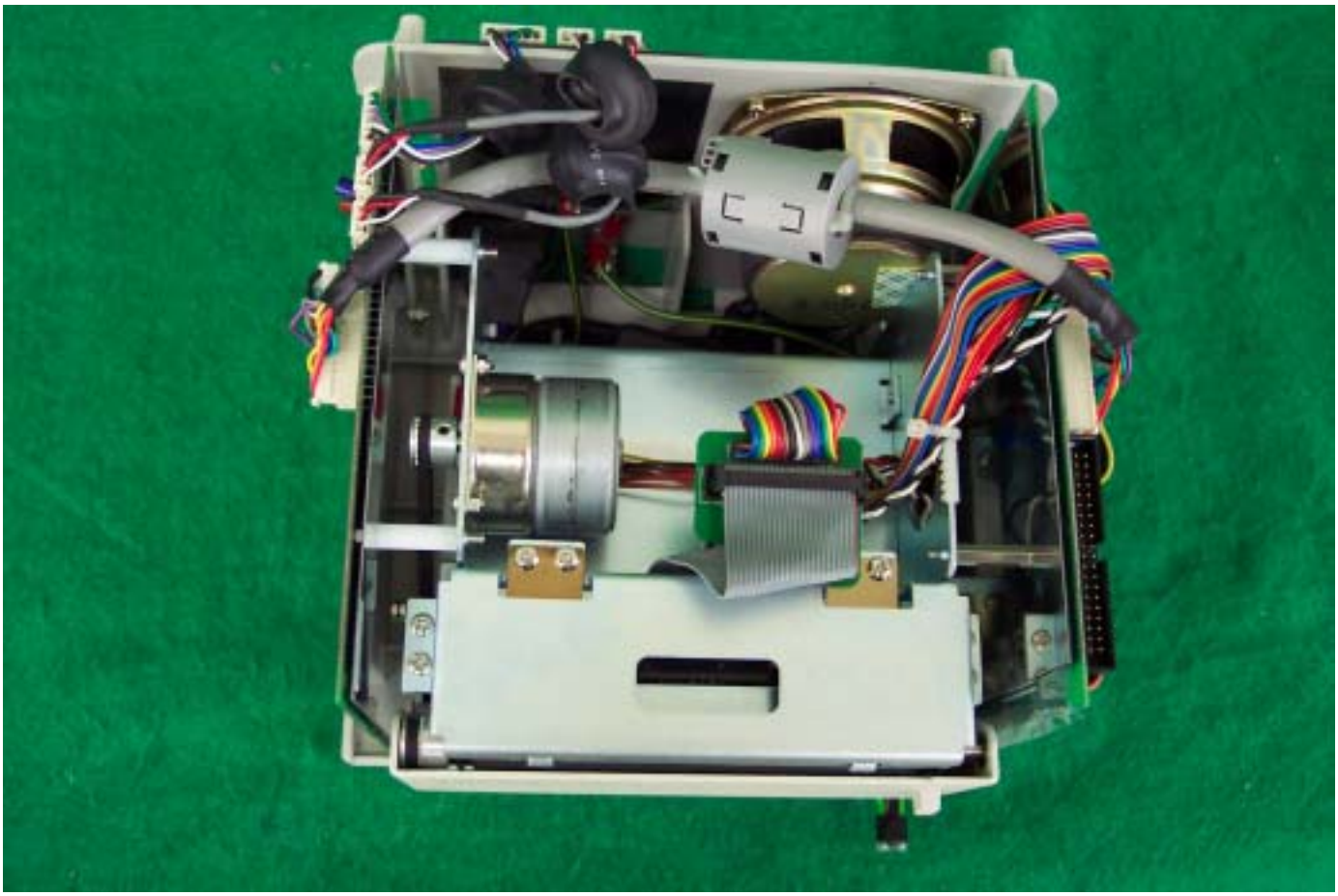
Switch position	NC S1 = 1, S7 = 1 Measured (µA)		SFC S1 = 0, S7 = 1 Measured (µA)		SFC S1 = 1, S7 = 0 Measured (µA)		Additional SFC* S1 = 1, S7 = 1 Measured (µA)	
S5	Before[1]	After[2]	Before[1]	After[2]	Before[1]	After[2]	Before[1]	After[2]
1	*28.3 /0.01*	*28.6 /0.01*	*28.5 /0.01*	*28.7 /0.01*	*30.6 /0.01*	*30.9 /0.01*	—	—
0	*28.1 /0.01*	*28.4 /0.01*	*28.2 /0.01*	*28.5 /0.01*	*30.8 /0.01*	*31.0 /0.01*	—	—

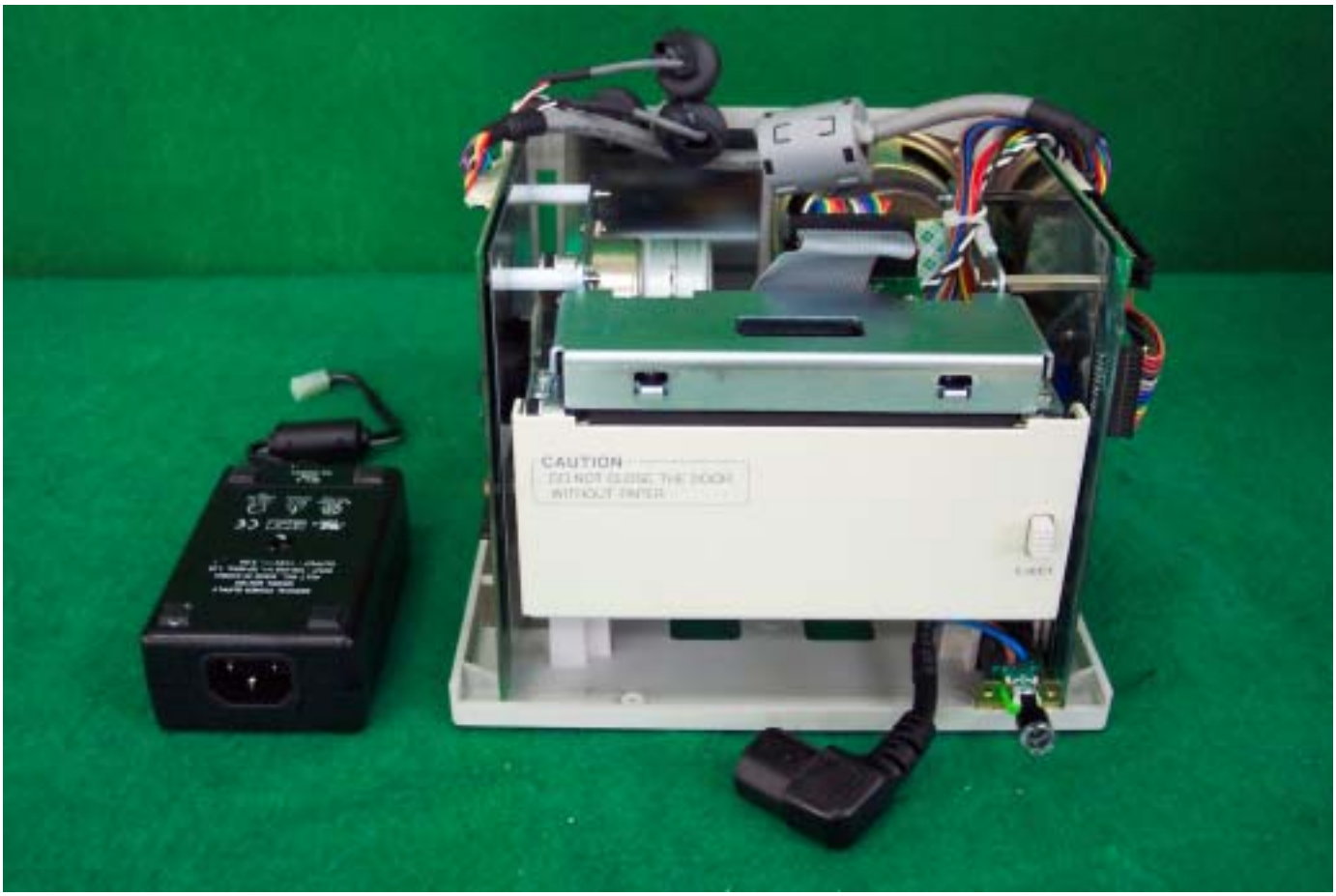
[1] and [2] = Before and after humidity preconditioning treatment.

Note:	S7 not used for Class II equipment	NC = Normal Conditions SFC = Single Fault Condition	1 = Switch Closed 0 = Switch Open	* = describe additional SFC according to Sub-clause 17 a in notes above








CAUTION